Changes in cognitive and neurological functions in patients undergoing cranioplasty for large craniectomy defects

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DEPARTMENT OF NEUROLOGICAL SCIENCES

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CERTIFICATE

This is to certify that the dissertation titled "**Changes in cognitive and neurological functions in patients undergoing cranioplasty for large craniectomy defects**" is the bonafide original work of Dr. Sanjay M Teelala submitted in partial fulfilment of the rules and regulations, for Branch-II M.Ch. Neurosurgery, Part-II examination of the Tamil Nadu Dr. M.G.R. Medical University to be held in August 2011.

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HYPOTHESIS

Patients following decompressive craniectomy for head injury with residual cognitive, behavioural, executive function or neurological deficits will show objective improvement in these parameters following cranioplasty.

AIMS AND OBJECTIVES:

The aims and objectives of this study are:

- To assess cognitive, behaviour and executive status of patients before and after cranioplasty using appropriate psychometric tests
- To assess motor power using MRC grading before and after cranioplasty

INTRODUCTION

Decompressive craniectomy has been performed in patients with lesions causing raised ICP that can not be directly treated, such as malignant brain edema caused by infarction or trauma. The aim of the procedure is to decrease the mass effect, thereby preventing brain ischemia, herniation and death.

Cranioplasty is a surgical procedure performed on patients where a portion of the skull removed during the decompressive surgery is replaced by autologus bone graft or artificial bone. The main objectives of cranioplasty are to restore the normal barriers protecting the intracranial structures, obtain a satisfactory cosmetic result and achieve a permanent or very durable reconstruction using biologically inert materials. However, there are many theories suggesting that cranioplasty may improve underlying physiological abnormalities caused by the lack of bone, and there are several reports of improvements in cognition and / or motor power following cranioplasty for large cranial defects. There has to date been no prospective study documenting improvement in patients with craniectomy defects and stable neurological deficits. Hence we undertook this prospective study to assess cognitive and neurological functions outcome of patients before and after cranioplasty using appropriate psychometric tests.

REVIEW OF LITERATURE

DECOMPRESSIVE CRANIECTOMY

High intracranial pressure (ICP) is the most frequent cause of death and disability after a severe traumatic brain injury (TBI). High ICP that is not caused by a surgically removable abnormality is usually treated in a graded manner by maintaining blood pressure and oxygenation, normothermia, sedation, CSF drainage, moderate hypocapnea, mannitol and other medical measures. When these fail to control high ICP, second-line therapies are initiated, which include barbiturate coma, hyperventilation and moderate hypothermia. When medical measures fail to control ICP, removal of generous segments of bone as a decompressive craniectomy can be used (opening the box), allowing the brain space to expand and consequently reduce high ICP (4).

The rationale for decompressive surgery is based on theMonro-Kellie law. According to this doctrine intracranial volume remains constant and volumetric compensations should be achieved by shifts in CSF, cerebral blood volume, or brain herniations. Removing a variable amount of bone, leaving the dura mater open or augmented by a duraplasty, is a fast and effective means of increasing intracranial volume, reducing elevated intracranial pressure and increasing the compliance of the intracranial space (5). The mean ICP decreased from 24 to 14.6 mm Hg after decompression, as reported by Aarabi et al (5).

The calculations of Münch et al (6) and Alexander et al (7) indicate that, decompressive craniectomy is efficacious in adding to the available intracranial volume. It significantly reduces intractable intracranial hypertension and improves brain tissue oxygenation, brain compliance, cerebral blood flow, pressure reactivity, and cerebrovascular

resistance. Each of these factors contribute to decreasing the pathophysiological cascades, particularly those augmented by ischemia, that result in secondary brain injury.

Types of surgical decompression

Decompressive craniectomy can be performed in two completely different situations:

- Prophylactic decompression or primary decompressive craniectomy is defined as any surgical decompression performed, with or without brain tissue removal, in patients undergoing surgery primarily for the evacuation of any type of intradural lesion. The aim of prophylactic craniectomy is not to control refractory ICP but to avoid expected postsurgical increases in ICP. (8).

- Therapeutic decompression or secondary decompressive craniectomy (S-DC) is defined as the procedure performed in patients in whom continuous ICP monitoring is conducted and in whom high ICP is refractory to medical treatment. This therapeutic option is used in some centres after first or second line therapeutic measures have failed to control ICP. (9).

Indications

Decompressive craniectomy is most commonly performed for traumatic brain injury (TBI) and ischemic stroke. The generally accepted guidelines (10, 11) for decompressive craniectomy are:

- Age < 50 years
- Brain swelling on CT scan, unilateral or bilateral with correlating clinical deterioration.
- No fatal primary brain injury with irreversible brainstem signs or herniation with neurological pons signs
- Refractory intracranial hypertension (> 30 mm Hg)
- Intracranial hypertension with deterioration in clinical status (GCS score, mydriasis), or an increase in pulsatility index with decrease in diastolic flow on transcranial Doppler ultrasonography (TCD).

Other reported entities that have been treated with DC include subarachnoid haemorrhage, venous thrombosis, toxoplasmosis, Reye's syndrome and encephalitis. Leaving the bone flap off if the brain is swollen and tense after the evacuation of a mass lesion is also a widely accepted practice . (10, 11)

Rationale of Decompressive Craniectomy in traumatic brain injury

Decompressive craniectomy as an option for managing refractory intracranial hypertension remains controversial but is rapidly regaining popularity. Despite many small series and case reports indicating the beneficial effect of secondary decompressive craniectomy on the outcome for patients with severe TBI and increased refractory ICP, no controlled clinical trial has proved that this procedure is more effective in improving outcome than maximal medical therapy in an adult population. However, it would be acceptable to include this procedure as a rescue therapy in patients for whom maximal medical treatment

has failed to control ICP (4). However, the only randomised controlled study was performed by Taylor et al in the paediatric age group (n = 27) and showed better outcomes both in terms of mortality and severe disability in the early decompressive craniectomy group (12). There are two ongoing randomized controlled trials of decompressive craniectomy (RescueICP and DECRA) that will allow further conclusions on the efficacy of this procedure in adults.

Experimental models in the late 1960s and early 1970s showed that decompressive surgery was highly effective in reducing mortality in unilateral brain swelling. However, Moody et al commented that although unilateral hemicraniectomy significantly improved mortality in dogs with unilateral brain swelling, "the quality of life among the survivors has not been good" (4). A Cochrane review (2006) recommended decompressive craniectomy may be justified in some children with medically intractable ICP after head injury but concluded there was no evidence to support its routine use in adults (4). EBIC and NICE (UK) recommend decompressive craniectomy as an option for refractory intracranial hypertension in all ages. The North American Brain Trauma foundation suggests decompressive craniectomy may be the procedure of choice in the appropriate clinical context and also considering the use of decompressive craniectomy in the first tier of TBI management (10, 11). Therefore, it is obvious that level 1 evidence is required to clarify which subset of patients with severe TBI would benefit from decompressive craniectomy but it is increasingly clear that use of decompressive craniectomy combined with modern neurointensive care offers the potential to save life with acceptable functional outcome. In many parts of the developing world where ICU facilities are limited, decompressive craniectomy has proved a cost-effective therapy and hence has always remained popular.

Complications of decompressive craniectomy

Complications of any procedure have major ramifications on the risk-benefit balance in decision making during evaluation of potential surgical candidates. An understanding of the pathophysiological events that accompany removal of a large piece of skull bone provides a foundation for understanding many of the complications associated with decompressive craniectomy. One of the reasons that decompressive craniectomy fell out of favour was intraoperative complications such as excessive blood loss, due to the fact that is was usually performed as an emergency by comparatively junior surgeons. Expansion of contusions, new subdural and epidural hematomas contralateral to the decompressed hemisphere and external cerebral herniation are the early postoperative complications of decompressive craniectomy for TBI. Within the first week following decompression, CSF circulation derangements manifest commonly as subdural hygromas. Paradoxical herniation following lumbar puncture in the setting of a large skull defect is a rare, potentially fatal complication that can be prevented and treated if recognized early. During the later phases of recovery, patients may develop a new cognitive, neurological, or psychological deficit termed syndrome of the trephined (36, 74).

SYNDROME OF THE TREPHINED (SINKING SKIN FLAP SYNDROME)

"Syndrome of the trephined" is an unusual syndrome in which neurological deterioration occurs following removal of a large skull bone flap. This syndrome is experienced by an unknown proportion of patients following large craniectomy and manifests as a combination of clinical symptoms which may include postural headaches and dizziness, various degrees of focal neurological deficits as well as impaired memory, concentration and cognitive function as first described by Grant and Norcross in 1939 (13). In the majority of

patients the symptoms are mild or moderate, but in some patients they significantly affect outcome and rehabilitation. Fodstad et al believed that only symptoms reduced or relieved by cranioplasty should be included in the definition of "syndrome of the trephined."(16).

In 1977 Yamura and Makino coined the term "syndrome of the sunken skin flap (SSFS)" as serious disabling neurological deficits and impairment of the general status with concave deformity and relaxation of the skin flap, which develop several weeks to months after large craniectomy. The neurological symptoms of SSFS they described included headache, vertigo, tinnitus, fatigue, loss of concentration, loss of memory, depression, dysphagia, apraxia, paresis of extremities, and convulsions. (14). They stated that "the syndrome of the sinking skin flap," should not be confused with the "syndrome of the trephined" or "the post-traumatic syndrome", which are mainly related to subjective complaints with significant psychic or neurotic components, excepting the presence of headache . The term "motor trephine syndrome" has been used to describe a delayed motor deficit occurring after decompressive hemicraniectomy, which reverses rapidly following cranioplasty (15).

Pathophysiology of the Syndrome

The first pathophysiological explanation for this syndrome was suggested by Gardner et al (27) in 1945, who felt that unlike the brain in the closed calvarium, in a trephined skull the brain pulsates with every alteration of arterial or venous pressure. According to this hypothesis, the in-and out pathologic movement of the brain is responsible for the symptoms, and therefore an immobilizing cranioplasty should relieve these symptoms.

Tsukasa et al proposed mechanism of SSFS was that a large cranial decompression is generally performed to reduce high intracranial pressure, and the cranial defect produced by craniotomy is directly affected by atmospheric pressure. As cerebral swelling improves, the skin at the cranial defect gradually sinks due to atmospheric pressure to deform cerebral tissue, resulting in decreased cortical blood perfusion and cerebral dysfunction (19).

There have been various other theories proposed for the occurrence of this interesting syndrome. A list of the theories that suggest reasons for neurological deficits after decompressive craniectomy are briefly summarized below:

1. ***Compression of the Underlying Cortex by an Infolded Scalp***: The removal of a large bone segment will leave the cranium with a flaccid area of scalp, which as a result of the gradient between atmospheric pressure and ICP will displace inwardly and press on the cortex (14, 17).

2. ***Changes in cerebral blood flow***: Radiological studies including xenon CT, perfusion CT, and dynamic CT imaging have shown improvement in CBF following cranioplasty at the site of the craniectomy, and at distant sites including the opposite hemisphere (14, 16, 18, 19). The reduction in CBF in the patient who undergoes a craniectomy can occur because of a deformity of intracranial structures, transmission of atmospheric pressure to the cerebral vasculature, and impairment of venous return as a result of local compression by the inwardly depressed scalp (14).

3. ***Cerebrospinal Fluid Hydrodynamics***: Fodstad et al observed changes in CSF hydrodynamic parameters that could be caused by the atmospheric pressure acting directly on the underlying cerebral tissue in the absence of a bone flap (16). In the upright position the ICP is normally negative in a closed skull. If there is a cranial defect present the ICP will tend to equalize with the atmospheric pressure, which in

turn will cause an increase in the ICP if the patient is in the sitting position. The removal of a large bone segment will leave the cranium with a more or less flaccid area that should contribute to changes in elastance and volume variables, and such changes were identified in their patients. Similar findings are noted in animal studies as well (18). This has been demonstrated by the fact that the neurological status of the patient can occasionally be strongly related to posture. Kumar et al described the worsening of left hemiparesis in the sitting position and sunken skin flap in the right frontoparietal region which improved with cranioplasty. (20). Nakamura et al noted prompt reversal of speech worsening and right hemiparesis after moving the patient to a horizontal or Trendelenburg position, along with restoration of the curvature of the scalp flap (21) . Guido and Patterson described 2 patients with a combination of a skull defect and a lumbar CSF leak with a dramatic change in neurological status related to posture. Both patients had blood injected into the epidural space of the lumbar theca, with excellent clinical recovery and a filling out of the sunken decompression site (21). Bijlenga et al found that, a patient with orthostatic sinking of the skin flap along with parkinsonian tremor, abducens nerve palsy, and mydriasis. All of these signs resolved soon after the patient lay down and after cranioplasty (23). Joseph et al reported a case of large craniectomy defect presented with low GCS with CT scan revealed worsening of the midline shift. There was reduction of midline shift and improvement in sensorium on lowering patient's head below the horizontal by 10° and patient made an excellent recovery with no evidence of neurological deficits after cranioplasty (24).

The goal of treatment in patient with the syndrome of the sinking skin flap is restoration of the pressure differential between the intracranial compartment and the atmosphere, which should correct the imbalances described above. In 1945 Gardner first

described clinical improvement after cranioplasty with tantalum mesh. Segal et al suggested that cranioplasty improves the neurological deficits by a decrease in local intracranial pressure, and correction of abnormal CSF dynamics (25). Another report suggested that the cranioplasty may affect postural blood flow regulation, cerebrovascular reserve capacity and cerebral glucose metabolism (26).

CRANIOPLASTY

Cranioplasty is the surgical correction of skull defects to protect the brain, to normalize intracranial pressure relationships and possibly alleviate neurological deficits resulting from cranial bony defects, and to provide reasonable cosmetic result (13, 15, 16, 17, 21, 24, 25, 27)

History

Cranioplasty, the repair of a skull vault defect by insertion of some object (bone or non-biological materials such as metal or plastic plates), is a well known procedure in modern neurosurgery(1), but repair of skull defects paralleled the practice of trepanation among ancient cultures(2,3).

Cranioplasty is among the oldest surgical procedures performed on the skull. Trauma, infections, tumors and compression caused by brain edema were some of the reasons for the removal of bone (3), and cranioplasty with varied materials was performed by many ancient civilizations dating back to 3000 BC, particularly the Inca period in Peru (28). The first recorded description of a true cranioplasty was made by Fallopius (1523-1562) and Petronius in 1565, who stated that the cranial bone could be replaced with a gold plate (29). The first successful bone graft cranioplasty was reported in 1668 by Job Janszoon van Meekeren, who successfully repaired a cranial defect using a dog's bone and definitely opened the way to the modern concept of cranioplasty(29). The number of cranioplasties increased during the 19th and 20th centuries when soldiers suffered cranial defects from war-related injuries (29).

Indications for cranioplasty

Cranioplasty is not only useful for cerebral protection and improvement of appearance, but it is also useful for improving neurologic symptoms. Grand et al(13) have performed an extensive literature review in neurological improvement after cranioplasty and given the indications for cranioplasty. They are:

- Severe headache and other symptoms of the syndrome of the trephined such as dizziness, undue fatigability, vague discomfort at the site of the defect, a feeling of apprehension and insecurity, mental depression and intolerance to vibration.
- Epilepsy, when the attacks originated from the injury that caused the defect.
- Those cases in which there is danger of trauma at the site of the defect.

- Cases that have an unsightly defect.
- Defects that pulsate unduly or that are painful.

Contraindications for cranioplasty

The contraindications are:

- The presence of any possible infection in either brain or bone.
- Increased cerebrospinal fluid pressure that is not easily reducible by lumbar puncture.

Timing of cranioplasty

From a practical point of view, the timing of reconstructive surgery is important. Several large centres, especially in developed countries, repair the skull defect during the same admission, once the ICP has become normal. Though Gardner stated that the syndrome of the trephined would not occur if skull defects were repaired immediately (27), it is generally agreed that the interval between complex wounds and cranioplasty should be between 3 and 6 months and as long as a year when there is a wound infection to avoid the complication of osteomyelitis. However, Fosdstad observed that patients who benefited most from cranioplasty were those in whom there were large defects near the dural sinuses with a concave deformity of the skin flap that allowed transmission of the atmospheric pressure directly to the cerebral cortex. Such cranial defects should therefore be repaired as early as possible (8).

In this context, one should recall the experience, published in 1979, of Berkley and coworkers, who reviewed 491 cranioplasties and found that complications of original injury and debridement increase the morbidity rate of cranioplasty and concluded that it was necessary to wait at least a year after penetrating or complex head injuries to ensure a good outcome (30, 32).

James et al advised not to attempt a primary repair after craniocerebral trauma, but to wait for at least two months if the wound heals by first intention. If there has been initial infection, plating should be deferred for at least six months, and longer in cases of infection with penicillin-resistant bacteria (42).

Cranioplasty and outcome

1. ***Cranioplasty and epilepsy:*** Cranioplasty has been said to exert a beneficial effect on posttraumatic epilepsy. For this reason, many surgeons have advocated the early repair of a cranial defect to prevent the occurrence of, or to reduce the frequency of seizures occurring after a head injury. (13, 16) On the other hand, some authors have found no convincing evidence of such a beneficial effect (30, 32, 38). Gardner found that, an early cranioplasty would prevent epilepsy since the "cranioplasty would eliminate progressive atrophy due to pulsations of the mobilized brain", and he reported that 6 out of 10 patients suffering from posttraumatic or postoperative epilepsy were relieved of seizures for 10-48 months and they found that electroencephalograms after cranioplasty were improved as compared to preoperative records (33).

2. ***Effect of cranioplasty on syndrome of trephined and motor deficits:*** It has proposed that cranioplasty should be performed not only for cosmetic and protective reasons, but also for post-traumatic syndromes as well as motor deficits that could be due to a bone defect. Yamaura et al reported that neurological deficits such as hemiparesis, sensory disturbance, aphasia and sinking flap syndrome improved dramatically after cranioplasty (14). Grantham and Landis stated that almost every partially aphasic patient became able to use more words after cranioplasty and one patient who was able to use only 10 words before cranioplasty became able to use 190 words within a week postoperatively (50).

   Liang W et al (35) reviewed 23 patients undergoing early cranioplasty (5-8 weeks after craniectomy) in the last 4 years with a detailed choice of patients, outcome of complications after head trauma and large craniectomy, as well as assessment of prognosis. The early outcome (1 month later) revealed most of the patients who had disturbances in conscioiusness before the cranioplasty recovered improved, with improvement in deficits as well. The longer term prognosis (18 months later) revealed that 17 patients made a good recovery (independent patients) in this series (74%), whereas four patients survived with a severe disability (17%) and two remained in a vegetative state (9%).

   Chang Hyun Oh (34) did a retrospective comparative study of outcomes between shunting after cranioplasty and cranioplasty after shunting in large concave flaccid cranial defect with hydrocephalus. The aim of this study was to evaluate the difference of outcomes between in the shunting after the cranioplasty (n=10, group 1) and the cranioplasty after the shunting (n=13, group 2) in a large flaccid cranial defect with posttraumatic hydrocephalus. The outcomes were compared in two groups 6

months later. Improvement of Glasgow outcome scale (GOS) was seen in 8 cases (80.0%) of total 10 cases in group 1, and 6 cases (46.2%) of 13 cases in group 2. Three (75.0%) of 4 cases with hemiparesis in group 1 and 3 of 6 cases (50.0%) in group 2 improved. All cases (2 cases) with decrease of visual acuity showed improvement in each group. Dysphasia improved in 3 of 5 cases (60%) in group 1 and 4 of 6 cases (66.6%) in group 2.

Stiver (36) evaluated patient demographics, injury characteristics, detailed motor examinations, and CT scans in 38 patients with long-term follow-up after decompressive hemicraniectomy for TBI. Ten patients (26%) experienced delayed contralateral upper-extremity weakness, beginning 4.9 ± 0.4 months (mean ± standard deviation) after decompressive hemicraniectomy. Motor deficits improved markedly within 72 hours of cranioplasty repair, and all patients recovered full motor function. The CT perfusion scans, performed in 2 patients, demonstrated improvements in cerebral blood flow commensurate with resolution of cerebrospinal fluid flow disturbances on CT scanning and return of motor strength. Comparisons between 10 patients with and 20 patients (53%) without delayed motor deficits identified 3 factors—ipsilateral contusions, abnormal cerebrospinal fluid circulation, and longer intervals to cranioplasty repair—to be strongly associated with delayed, reversible monoparesis following decompressive hemicraniectomy. Delayed, reversible monoparesis, also called motor trephine syndrome, is common following decompressive hemicraniectomy for TBI.

Erdogan et al (37) studied eighteen patients who underwent cranioplasty, and found that in fourteen patients with syndrome of trephined and five patients with hemiparesis had improvement after cranioplasty. Primrose reviewed 42 cases, I9 of

whom were cured of their complaints, eight improved, five unchanged, and two made worse. Shuttleworth reported seven cases, four of whom were relieved of their complaints and two improved, while one was the same as before operation(13). Termier was able to follow 63 cases that had been done over 25 years and he felt that only a few epileptics or psychotic patients had been improved, but that the majority of the trephine syndromes had been cured or greatly benefited(13).

Boinet reviewed 41 cases of cranioplasty and 95 cases of cranial defect that had not been repaired and found that there were no significant differences between the symptomatology of the cases whose defect had been filled and those in whom it was still open (13). Lockhart et al stated that precranioplasty headaches, visual disturbances, difficulty in speech, convulsions, weakness of extremities and mental impairment were not changed by the repair of the cranial defect. (30, 40)

3. ***Effects of cranioplasty on cerebral hemodynamics:*** Restoration of cerebral hemodynamics as an explanation for recovery after cranioplasty were proposed by some studies. Yoshida et al studied cerebral blood flow and metabolism in seven patients with stable 133Xe computed tomography and 31P MRS and demonstrated the increase of cerebral blood flow and improvement in neurological deficits after cranioplasty (38). Winkler et al investigated cerebral blood flow reactivity with TCD and cerebral glucose metabolism with positron emission tomography in 12 patients and reported that cranioplasty has a role in improvement in cerebral blood flow as well as improvement of cerebral vascular reserve capacity (26).

   Thirteen patients were studied by Chung-Ching Chio to assess postoperative changes in neurological status and blood flow velocity using TCD. The results showed

significant improvements after cranioplasty in GCS, arm muscle power, and Barthel Index. While the CBF velocities tended to increase after cranioplasty, only the increase in the non-lesion side middle cerebral artery (MCA) was statistically significant. The interval from decompressive craniectomy to cranioplasty and neurological status change before and after cranioplasty was significantly negatively correlated so that they conclude that cranioplasty can improve neurological status, and it should be performed as earlier as edema has resolved (40).

Complications of cranioplasty

Complications are relatively common after cranioplasty, being reported up to 23.6% of cases (44). Postoperative infection, osteomyelitic bone flap and necrosis of the flap are the commonest (14, 43, 44, 45). However there are some report of cerebrospinal fluid fistula from fractured acrylic cranioplasty plate (41), fracture of the resin plate(14), resorption of preserved autografts and calvarial hemangioma at site of cranioplasty (42).

The majority of complications due to latent foci of infection that have made themselves manifest after cranioplasty in view of presence of foreign body. Currently, an incidence of infectious complications less than 5% is considered acceptable (27). The incidence of infection has been reported as 3.3% (14), and 3.7% (30). The infection rate of cranioplasty depends on several factors: material used, site and size of the defect, previous wound infection and others (44).

The incidence of late complications in a pediatric population was reported as high as 23%. It was related to the thinner scalp, continued skull growth and greater activity level of the child (45). However age was not a significant risk factor in the adult population (46).

Although the autogenous bone remains the preferred option, infection and graft absorption are common complications of the cranioplasty using frozen autogenous bone graft (46, 47). The infection rate of the autogenous bone was reported as 0-33% (44, 47). PMMA is the most frequently used alloplastic material. The infection rate is rather lower than the autogenous bone graft, being reported as 1-16% (44, 48).

The size of the defect may influence on the infection rate (45). Park et al defined a small defect as a size of less than 75 cm^2 and a large defect as more than 125 cm^2. The infection rate was 6.9% in small defects, 11.1% in middle sized defects, and 37.5% in large defects. The size was the only difference that reached statistical significance in his study (44).

Berkley and colleagues in 1979 found that cranioplasties taking place 1–6 months after craniectomy had the highest complication rate (7.9%) and those performed 12–18 months after craniectomy had the lowest complication rate (4.5%) (30).

Reid Gooch has done analysis of 62 cases after cranioplasty and stated that patients undergoing a bifrontal craniectomy are at significantly increased risk for postcranioplasty complications, including the need for reoperation as compared to unilateral frontotemporoparietal (FTP) cranioplasty (49). This is probably due to the proximity of the skull defect to the paranasal sinuses (44, 45, 47, 49).

Materials used for cranioplasty

The development of ideal cranioplasty materials has been a continuing medical and bioengineering challenge. To be suitable for cranioplasty, it must meet several criteria. The material should be (51):

- Malleable, to achieve a good cosmetic result

- As strong as bone, to secure adequate protection
- Lightweight, to avoid patient discomfort
- Chemically inert and noncarcinogenic
- Nonferromagnetic, to allow CT scanning and magnetic resonance imaging to be performed
- As inexpensive as possible
- In children, the material should be able to allow the skull to grow .

Certain factors determine whether autologous bone grafts and / or biomaterials should be used in a particular case. Bone grafts appear to have a low infection rate in most studies reviewed, and the stimulatory effect of autologous bone transplants on local bone regeneration is also important (51, 52, 53, 54). The disadvantages include enhanced morbidity and risk for complications from donor site when harvesting the graft (55, 56), resorption of transplanted bone (57, 58) and availability of limited amount of donor bone for the reconstruction of large defects. On the other hand, the general advantages of using biomaterials include no donor-site morbidity, shortening of operating time and hospital stay (56). The disadvantages are higher infection rates in some studies and costs (44, 56 , 59, 60). However, the eventually decreased morbidity and shortening of hospital stay may tilt the balance towards the use of biomaterial.

Materials used for cranioplasty include:

- Bone grafts
    - Autografts
    - Allografts.

- Biomaterials
    - Methyl methacrylate (PMMA)
    - Hydroxyapatite
    - Calcium phosphate
    - Porous polyethylene
    - Titanium
    - Combined biomaterials.

Sanan and Haines (62) published an excellent historical review of cranioplasty and listed the materials and techniques that have been used from ancient times to the present. They conclude that allografts, which have been used for centuries, carry resorption and infection rates that are too high. Use of metallic and nonmetallic substitutes may also lead to several problems. But still PMMA is the most frequently used alloplastic material (44, 51, 63, 64) and has long been used at our institution. Its advantage are ease of use, malleability and low cost, but being a foreign material may cause significant inflammation, producing a membrane at the interface between the host bone and the cranioplasty device (51).

In recent years attempting to stimulate new bone formation by osteoinduction using growth factors has been tried. The use of porous ceramics may be ideal because they can provide osteoconduction in addition to the inductive effects provided from impregnated cytokines. Bone morphogenetic proteins (BMPs) have been used in a few human studies with promising results (61). However the introduction of biomaterials, including compounds with osteoinductive growth factors, for cranial bone repair needs to be accompanied with good prospective comparative studies to obtain conclusive results and create guidelines (61).

MATERIALS AND METHODS

STUDY DESIGN

A prospective cohort interventional study design was employed to evaluate the post cranioplasty changes in cognition, executive functioning, behaviour, and motor power of selected traumatic brain injury patients with large frontotemporoparietal or bifrontal craniectomy defects following cranioplasty. The assessments were done during the pre-surgical period evaluation and every month during the follow up of three months.

SAMPLING TECHNIQUE

In this study purposive sampling technique was used to select the sample. This method allows selecting individuals units by purposive method.

SAMPLE SIZE CALCULATION

The sample size for the study was determined to be 20 traumatic brain injured patients with decompressive craniectomy defect. The sample size calculation was done by using the below formula.

$n=4pq/d^2$

Using p= 27.7 from a previous study where 'p' was the proportion of patients who improved after cranioplasty; q= 72.3 from a previous study where 'q' was the proportion of the patients who did not improve after cranioplasty, where d = 19, then n = 21.

STUDY SITE AND PARTICIPANTS

The study was conducted in the Department of Neurological Sciences, Brain Injury Clinic (BIC) and the Department of Physical Medicine and Rehabilitation, Christian Medical College, Vellore. Head injured patients with decompressive craniectomy defects who were being followed up in the BIC for were selected for the study using the following criteria.

INCLUSION CRITERIA

1. Traumatic brain injury patients with frontotemporoparietal or bifrontal craniectomy defect.
2. Stable Addenbrook's Cognitive Evaluation Scale-Revised (ACE-R) score and neurological deficits.
3. Age between 15 to 60
4. Patients (or caregivers when necessary) who were willing to participate

EXCLUSION CRITERIA

1. Patients in whom the Addenbrook's Cognitive Evaluation Scale-Revised (ACE-R) could not be administered.
2. Patients with a pre-morbid history of psychiatric illness or dementia.
3. Patients with contraindications for cranioplasty.

OUTCOME MEASURES

Quantitative measures

1. ***Addenbrook's Cognitive Evaluation Scale – Revised:*** (see appendix)It is a brief neuropsychological test used for assessing cognition. It is reliable and sensitive in the early stages of dementia, and capable of differentiating subtypes of dementia including Alzheimer's disease, frontotemporal dementia, progressive supranuclear palsy and other parkinsonian syndromes. The test was originally developed in the year 2000 (65) and revised in 2006 (66), and has been adapted and validated in many languages including the South Indian language of Malayalam, (67) and the cut-off scores have been found useful across India. It has 5 subtests

    - Attention & orientation
    - Memory
    - Fluency of speech
    - Language
    - Visuospatial ability

    The alpha coefficient of the ACE-R is found to be 0.80 and its concurrent and convergent validity has been established (66).

2. ***Mayo-Portland Adaptability Inventory-4:*** (see appendix)It was designed to assist in the clinical evaluation of people during the post acute period following acquired brain injury. MPAI-4 items represent the range of physical, cognitive, emotional,

behavioral, and social problems that a patient might develop after brain injury. The MPAI-4 consists of three subscales:

- Ability (sensory, motor, and cognitive abilities)
- Adjustment (mood, interpersonal interactions)
- Participation (social contacts, initiation, money management).

The test assesses highly developed and well-documented psychometric properties. A satisfactory overall person and item reliability has been found. Concurrent (68) and predictive validity (69) of the MPAI has been demonstrated in a number of studies.

3. ***Key Behaviour Change Inventory (KBCI):*** (see appendix) (70)it is a 64-item test that was developed to assess executive, interpersonal, and emotional functioning behaviors following TBI. The eight subscales of the test are to test for:

    - Unawareness
    - Inattention
    - Impulsivity
    - Apathy
    - Interpersonal difficulties
    - Communication problems
    - Emotional adjustment
    - Somatic difficulties.

    It has four questionnaires (pre and post intervention version for patients, and the same for the patient's caregiver). The psychometric properties of the test found adequate reliability (internal consistency coefficients range from .82 to .91), and it also has good content and construct validity (70).

4. ***Multiple Errands Test (MET):*** This is a test to assess the executive functioning of a person by asking the subject to carry out activities in real life situations. It assesses

    - Planning
    - Prospective memory
    - Multi tasking.

It is a 6 element test in which the subject has to organize their activities in order to carry out six tasks in a limited time period and without breaking certain rules. The task includes shopping, finding out certain information, and being in a particular place at a particular time. The modified version of MET has been used for the current study (see appendix) (71). The inter-rater reliability of the test ranges from .81 to 1.00 (72). Discriminant validity was satisfactorynfor the test (71). The errors were categorised using the definitions offered by Shallice and Burgess (see appendix) (73), namely:

- Inefficiencies
- Rule breaks
- Interpretation failure
- Task failure

This task was performed with the help of a psychologist.

5. ***Medical Research Council (MRC) grading:*** This is a reliable and validated scale for assessing muscle weakness. Each muscle group is graded as follows:

    - 0 - no movement
    - 1 - flicker of movement perceptible in the muscle
    - 2 – full range of movement with gravity eliminated
    - 3 – full range of movement against gravity

- 4 - can move against gravity & some resistance exerted by examiner
- 5 - normal power

Qualitative Measure

Both the patient and caregiver were asked to fill a three point scale question (see appendix) to assess their subjective opinion about the improvement after cranioplasty.

SELECTION OF PATIENTS AND ASSESSMENT PROCEDURE

Head injured patients after decompressive craniectomy are regularly followed up in the Brain Injury Clinic (BIC) by a multidisciplinary team. They were consecutively selected and assessed by clinical interview and recruited for the study by using inclusion and exclusion criteria. The assessment began with administration of the ACE-R test, primarily for assessment of cognition. If the cognitive scores were within normal limits (above 82) the patient was administered the Key Behavioural Change Index (KBCI) test for behavioural assessment. If the KBCI results were within normal limits the patient was administered the Multiple Errands Test (MET) to test executive functions. All patients were assessed using the MPAI-4 questionnaire (except the initial 4 recruited) and motor power using MRC grading.

There was no definite protocol on how long after the decompressive craniectomy the cranioplasty was carried out. The difficulty we faced in trying to demonstrate the benefits of cranioplasty were to separate the effects of the procedure from the natural history of improvement. We attempted to do so by performing the cranioplasty after a minimum period of six months after the initial surgery, and operating on patients only when their

neuropsychological scores and motor power had remained unchanged for 2 consecutive assessments at least one month apart.

ETHICAL ISSUES

The ethical concerns of this study were addressed using the following measures:

1. Written informed consent from the patient or primary caregiver (appendix A) for participating in the study was obtained ensured voluntary participation.
2. Reversible anonymisation as well as restricted access and disclosure of the data ensured the privacy of patients.
3. The Institutional Review Board and Ethics Committee of Christian Medical College had reviewed and approved for the study.

STATISTICAL PARAMETERS

The data collected for study was coded and verified thoroughly. Subsequently, using SPSS-16 (Statistical Package for Social Science) all the data was analyzed in three steps. In the first step, the basic characteristics of study population were outlined using descriptive statistical parameters. In the second stage, for the main analysis of the study (pre and post cranioplasty) Wilcoxon signed rank correlation was employed to assess significance. In the third stage a subanalysis using Kruskal Wallis and Mann Whitney U test was employed to find out the improvement based on the original admission GCS, interval between decompression and cranioplasty and location of craniectomy defect. The level of significance considered for all statistical parameters for the present study was .05.

RESULTS

The study results are presented in tabular form below, and each table described in the accompanying text. Table 1 shows the basic characteristics of the study population. Though the sample size required was 20, and 20 patients were recruited, complete follow up assessment could only be completed for 15. Nine (60.0%) patients were males and 6 (40%) were females. The age of the patients was categorized into three groups: 6 patients were 15-30 years (40.0%), 8 patients (53.3%) were 31-50 years and one patient (6.7%) was above 51 years. The patients who participated in the study had their injury between 7 months to 24 months before the date of cranioplasty. This interval was again categorised into three groups: 7- 12 months (6 patients, 40.0%), 13 – 18 months (5 patients, 33.3%) and 19-24 months (4 patients, 26.7%). The patients were also divided based on the GCS score at the original admission into mild head injury (3 patients, 20.0%), moderate head injury (10 patients, 66.7%) and severe head injury (2 patients, 13.3%). On the basis of type of decompressive craniectomy patients had one of bifrontal (4 patients, 26.7%), right (6 patients, 40%) or left (5 patients, 33,3%) frontotemporoparietal decompressive craniectomy.

Table 1: Basic Characteristics of Study Population

Variables	Category	Frequency (N=15)	Percentage
Sex	Male	9	60.0
	Female	6	40.0
Age	15-30	6	40.0
	31-50	8	53.3
	51 & above	1	6.7
Duration between decompressive surgery and cranioplasty	7-12 months	6	40.0
	13-18 months	5	33.3
	19-24 months	4	26.7
GCS at original admission	Mild	3	20.0
	Moderate	10	66.7
	Severe	2	13.3
Type of decompressive craniectomy	Bifrontal	4	26.7
	Right FTP	6	40.0
	Left FTP	5	33.3

Table 2 shows the Median, Interquartile range, z value, and P-Values of ACE-R. The number of patients who were administered ACE-R is 15. None of the subscales of the test demonstrated a significant difference after surgery. The P-Value of tests of attention & concentration was .58 (pre op median: 18.00; post op median: 18.00). The P-Value of memory was .13, which suggests no significant difference between pre and post surgery (pre op median: 25.00; post op median: 26.00). The result of the subscales for fluency (pre op median: 7.00; post op median: 8.00; and P-Value .08), language (pre op median: 25.00; post op median: 25.00; and P-Value .35) and visuospatial functions (pre op median: 16.00; post op median: 16.00; and P-Value .49) also showed no significant improvement. By contrast, there

was a significant improvement in the total ACE-R score after cranioplasty (pre op median: 90.00; post op median: 92.00; and P-Value .02).

Table 2: Median, Interquartile range, Z value and P-Values of ACE-R

Variables	Median (N=15)		Interquartile Range		Z-Value	P-Value
	Pre Op	Post Op	Pre Op	Post op		
Attention & Orientation	18.00	18.00	18.00-18.00	18.00-18.00	-5.57	.58
Memory	25.00	26.00	22.00-26.00	24.00-26.00	-1.52	.13
Fluency	7.00	8.00	4.00-8.00	6.00-9.00	-1.74	.08
Language	25.00	25.00	24.00-26.00	25.00-26.00	-.94	.35
Visuospatial	16.00	16.00	15.00-16.00	15.00-16.00	-.69	.49
Total Score	90.00	92.00	82.00-92.00	87.00-94.00	-2.25	*.02

*P-Value significant at .05 level

Graph 1: Pre and Post op changes of ACE-R Total Score(Mean value)

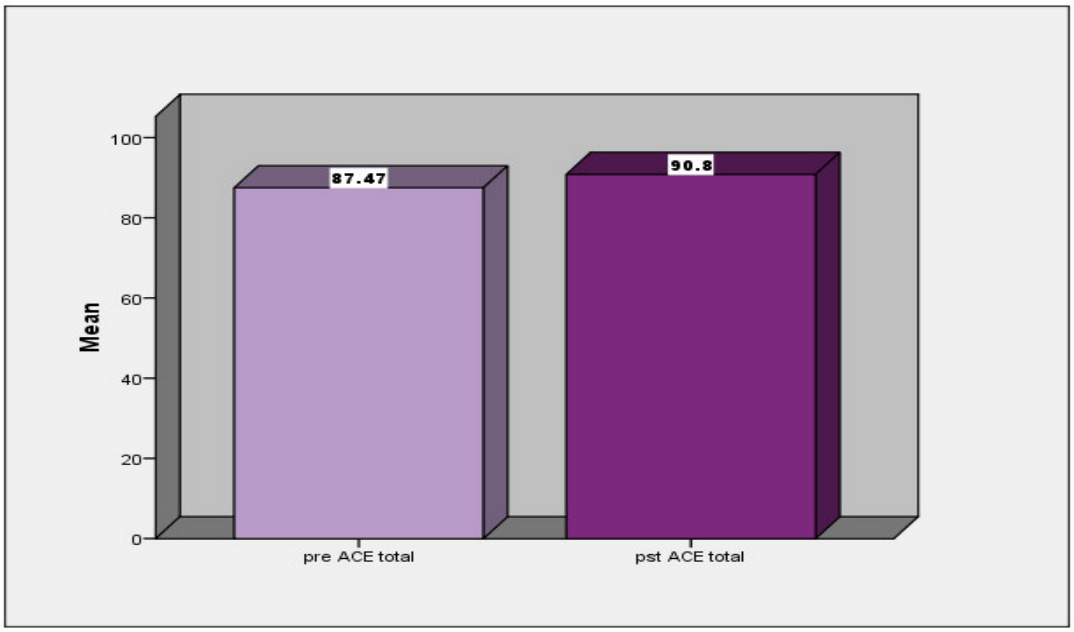


Table 3 below shows the results of sub scales and total score of MPAI-4. The total number of patients for whom MPAI administered was 11. This test was introduced into the Brain Injury Clinic protocol only after the first 4 patients in this study had already undergone surgery. All subscales and the total score showed improvement after surgery. The ability subscale (pre op median: 1.00; post op median: .00; pre op interquartile range: 00-4.00; post op interquartile range: 00-1.00; Z-Value -2.02; and P-Value .04), adjustment (pre op median: 5.00; post op median: .00; pre op interquartile range: 1.00-10.00; post op interquartile range: .00-4.00; Z-Value -2.69; and P-Value .01), and participation (pre op median: 4.00; post op median: .00; pre op interquartile range: 2.00-7.00; post op interquartile range: .00-4.00; Z-Value -2.37; and P-Value .02) all showed significant changes, as did the total score (pre op median: 9.00; post op median: 3.00; pre op interquartile range: 5.00-18.00; post op interquartile range: 1.00-4.00; Z-Value -2.93; and P-Value .00).

Table 3: Median, Interquartile range, Z value and P-Values of MPAI-4

Variables	**Median N=11**		**Interquartile Range**		**Z-Value**	**P-Value**
	Pre Op	**Post Op**	**Pre Op**	**Post op**		
Ability	1.00	.00	.00-4.00	.00-1.00	-2.02	*.04
Adjustment	5.00	.00	1.00-10.00	.00-4.00	-2.69	*.01
Participation	4.00	.00	2.00-7.00	.00-4.00	-2.37	*.02
Total MPAI Score	9.00	3.00	5.00-18.00	1.00-4.00	-2.93	**.00

*P-Value significant at .05 level

**P-Value significant at .01 level

Graph 2:Pre and Post in MPAI-4 Total(Mean value).

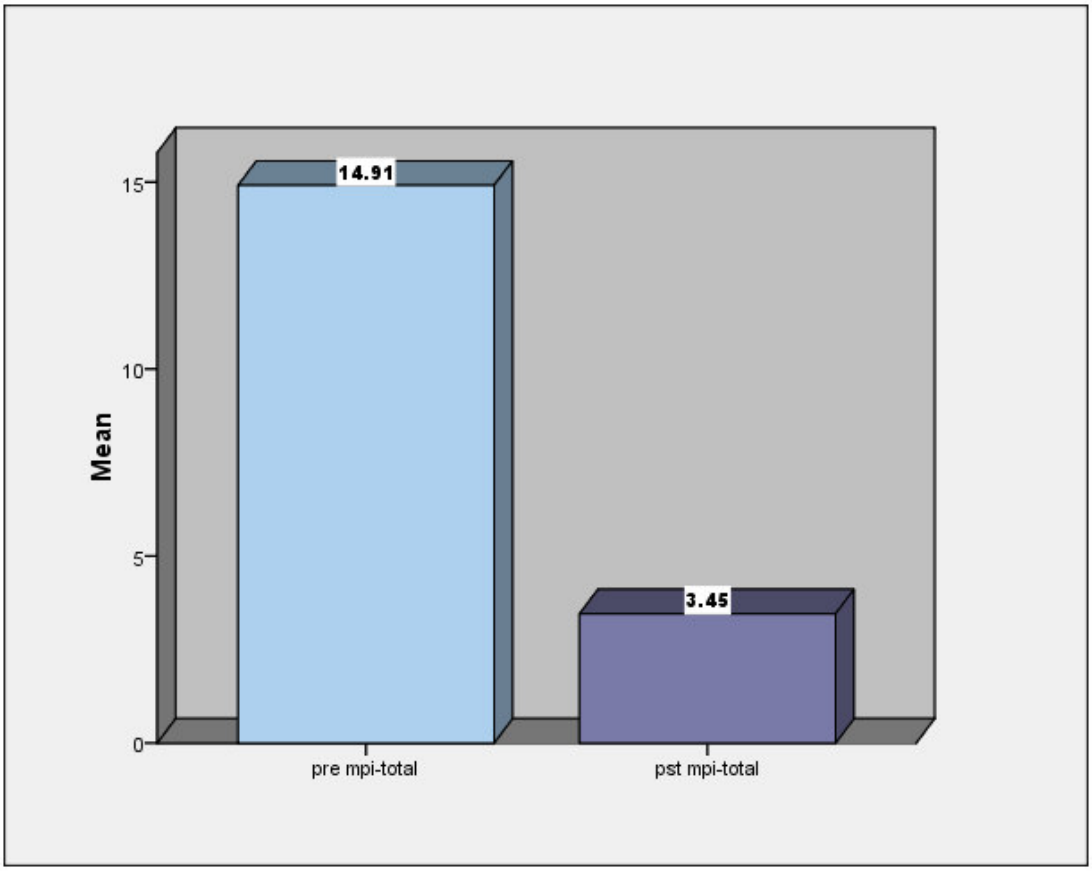


Table 4 presents the median, interquartile range, Z value and P-values of KBCI of the patients. The value of the inattention subscale suggests no significant improvement after cranioplasty (pre op median: 14.00; post op median: 10.00; and P-Value .78). Impulsivity (pre op median: 14.00; post op median: 12.00; and P-Value .07), unawareness (pre op median: 16.00; post op median: 13.00; and P-Value .12), interpersonal problems (pre op median: 14.00; post op median: 13.00 and P-Value .62) and communication (pre op median: 15.00; post op median: 12.00; and P-Value .10) scales also showed no statistically significant change after surgery. However the apathy (pre op median: 15.00; post op median: 12.00; and P-Value .01), somatic (pre op median: 14.00; post op median: 12.00; and P-Value .03) and

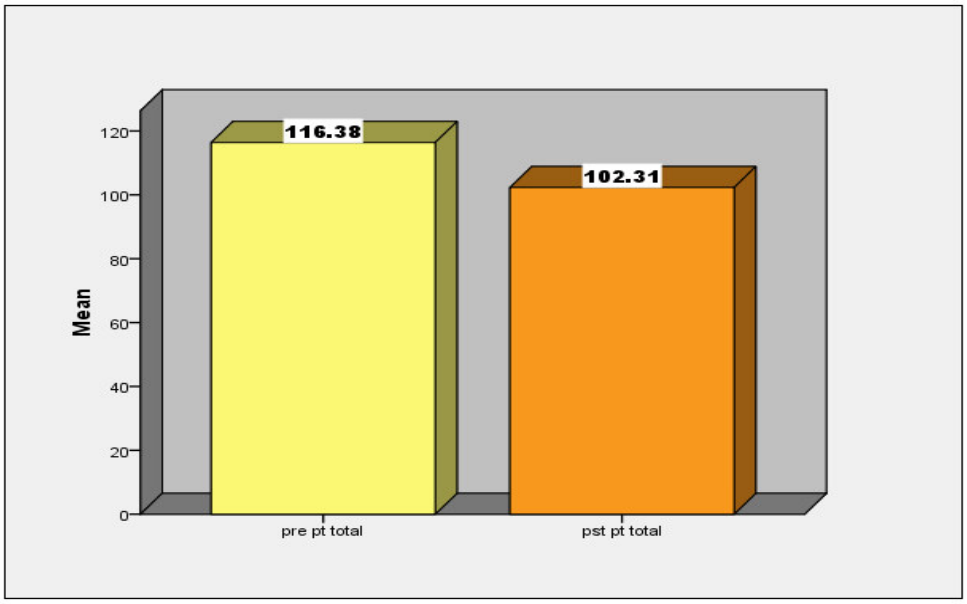
emotional (pre op median: 15.00; post op median: 10.00; and P-Value .05) subscales showed significant improvement after cranioplasty. The total score of KBCI also reveals no significant change after surgery (pre op median: 105.00; post op median: 95.00; and P-Value .06).

Table.4: Median, Interquartile range, Z value and P-Values of KBCI of Patients

Variable	Median (N=13)		Interquartile Range		Z-Value	P-Value
	Pre Op	Post Op	Pre Op	Post op		
Inattention Problems	11.00	10.00	9.00-13.50	8.50-13.50	-.28	.78
Impulsivity	14.00	12.00	10.00-18.00	10.00-15.00	-1.79	.07
Apathy	15.00	12.00	12.50-17.50	10.00-14.50	-2.81	*.01
Unawareness problems	16.00	13.00	11.50-20.00	11.00-17.00	-1.54	.12
Interpersonal Problems	14.00	13.00	11.00-18.00	11.50-17.00	-.49	.62
Communication problems	15.00	12.00	11.00-18.00	10.00-16.50	-1.65	.10
Somatic problems	14.00	12.00	12.00-20.50	10.00-15.50	-2.21	*.03
Emotional problems	15.00	10.00	13.00-18.00	9.00-17.00	-2.01	*.05
Total score	105.00	95.00	94.00-138.50	85.00-122.50	-1.89	.06

*P-Value significant at .05 level

Graph 3: Pre and Post operative KBCI Patient's Total score(Mean value).



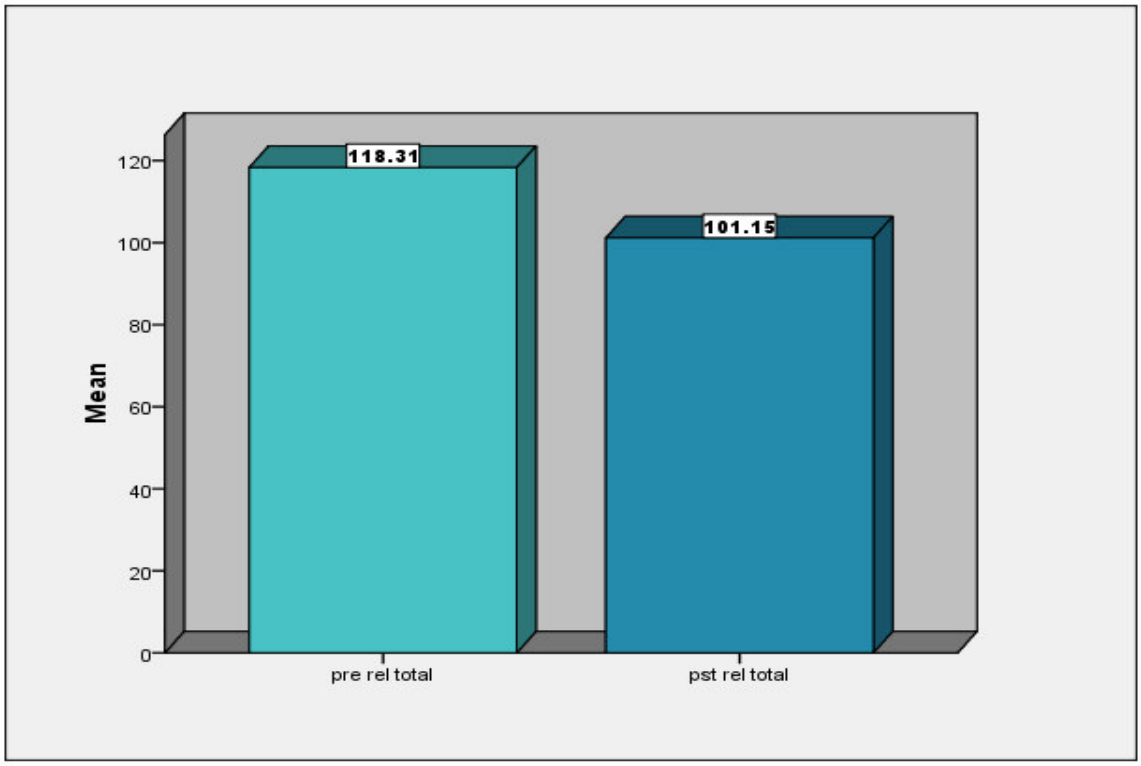
The fifth table shows the median, interquartile range, Z value and P-values of KBCI of the caregivers. Most of the subscales of the KBCI, namely inattention, impulsivity, apathy, unawareness, interpersonal problems and emotional problems showed no significant improvement after cranioplasty (inattention: pre op median: 11.00; post op median: 10.00; and P-Value .37, impulsivity: pre op median: 13.00; post op median: 11.00; and P-Value .31, apathy: pre op median: 13.00; post op median: 10.00; and P-Value .08, unawareness: pre op median: 14.00; post op median: 11.00; and P-Value .10, interpersonal problems: pre op median: 13.00; post op median: 11.00; and P-Value .24, and emotional problems: pre op median: 14.00; post op median: 12.00; and P-Value: .22). On the other hand, the subscales for communication (pre op median: 13.00; post op median: 10.00; and P-Value .05) and somatic problems (pre op median: 19.00; post op median: 12.00; and P-Value .02) showed a statistically significant difference after surgery, as did the total score (pre op median: 104.00; post op median: 88.00; and P-Value .03).

Table.5: Median, Interquartile range, Z value and P-Values of KBCI of Relative

Variable	Median (N=13)		Interquartile Range		Z-Value	P-Value
	Pre Op	Post Op	Pre Op	Post op		
Inattention Problems	11.00	10.00	9.00-13.50	9.00-14.50	-.89	.37
Impulsivity	13.00	11.00	10.00-18.00	8.50-16.00	-1.02	.31
Apathy	13.00	10.00	12.50-17.50	8.00-15.50	-1.73	.08
Unawareness problems	14.00	11.00	11.50-20.00	9.00-14.00	-1.64	.10
Interpersonal problems	13.00	11.00	11.00-18.00	11.00-14.00	-1.17	.24
Communication problems	13.00	10.00	11.00-18.00	8.00-12.50	-1.94	*.05
Somatic problems	19.00	12.00	12.00-20.50	11.00-17.50	-2.28	*.02
Emotional problems	14.00	12.00	13.00-18.00	12.00-14.00	-1.23	.22
Total score	101.00	88.00	94.00-138.50	78.00-112.00	-2.12	*.03

*P-Value significant at .05 level

Graph 4: Pre and Post operative changes of KBCI Total Score for Caregivers(Mean value).



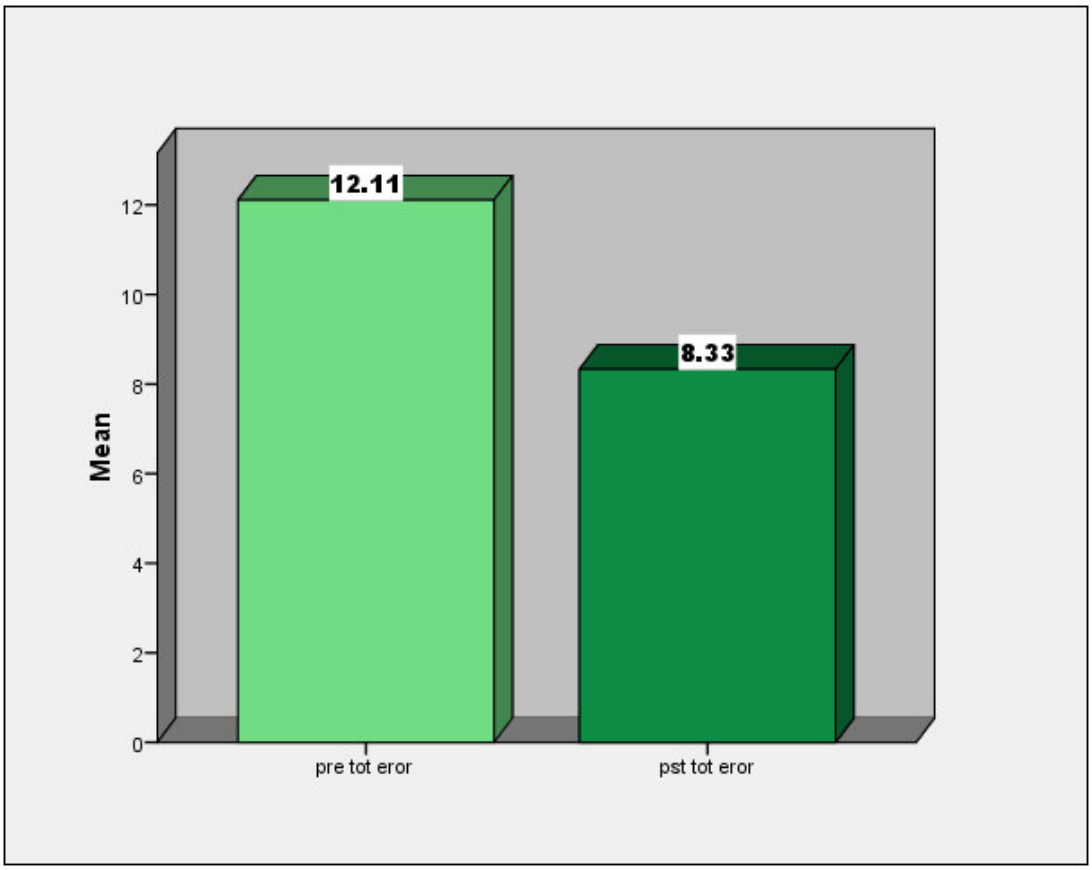
The results of MET, median, interquartile range, Z value and P-values are given below in Table 6. The P-values of some subscales of MET, namely inefficiency, task failures and interpretation failure showed no statistically significant change after cranioplasty (inefficiency: pre op median: 1.00; post op median: 1.00; and P-Value .12, task failures: pre op median: 5.00; post op median: .4; and P-Value .53, interpretation failure: pre op median: 1.00; post op median: 2.00; and P-Value .48). But the P-Values and median of rule breaks and the total error of MET shows significant improvement after surgery (rule breaks: pre op median: 3.00; post op median: .00; and P-Value .05, total score: pre op median: 10.00; post op median: 6.00; and P-Value .04).

Table.6: Median, Interquartile range, Z value and P-Values of MET

Variable	Median (N=15)		Interquartile Range		Z-Value	P-Value
	Pre Op	Post Op	Pre Op	Post op		
Ineffiency	1.00	1.00	.00-3.00	.00-1.00	-1.55	.12
Rule Breaks	3.00	.00	.50-5.00	.00-1.00	-1.96	*.05
Task Failures	5.00	4.00	3.00-7.00	2.50-6.50	-.06	.53
Interpretation Failures	1.00	2.00	1.00-3.00	1.00-2.50	-.70	.48
Total	10.00	6.00	7.50-17.00	5.00-12.50	-2.10	*.04

*P-Value significant at .05 level

Graph 5: Pre and Post operative changes in MET Total Errors(Mean value).

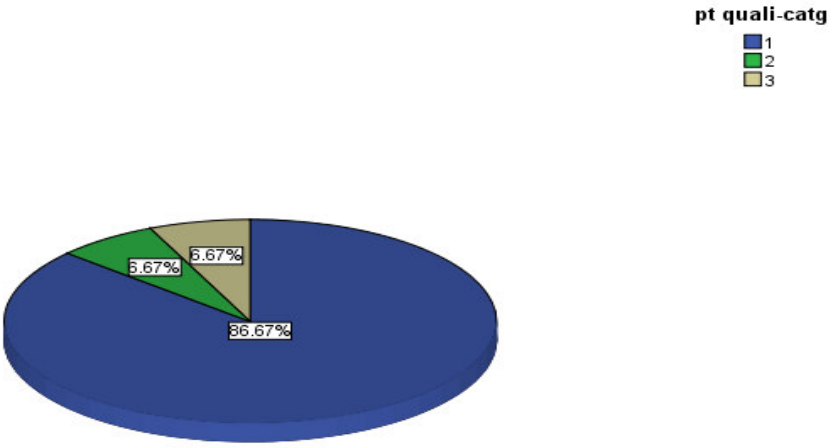


As part of qualitative assessment, a self evaluation of improvement after cranioplasty was recorded after 3 months and results, frequency and percentages provided in table 7. In patient's group 13 (86.7%) reported improvement, 1 patient (6.7%) reported worsening after surgery and 1 patient (6.7%) reported no change. The same questions were administered to the caregivers, and 11 (73.3%) reported improvement while 4 (26.7%) there was no change. None of the caregivers reported any worsening.

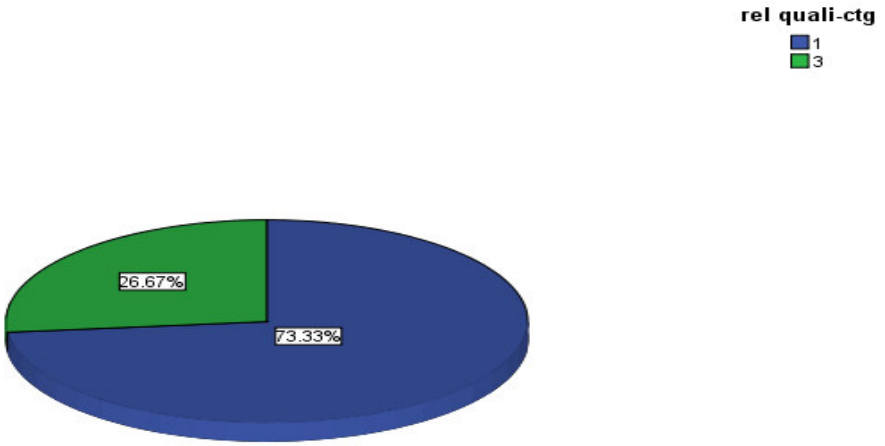
Table.7 Results of Qualitative assessment of Both Patient and their Relatives

Qualitative Assessment		**Frequency (N=15)**	**Percentage**
Patient's	Improved	13	86.7
	Worsened	1	6.7
	Same as before	1	6.7
Relative's	Improved	11	73.3
	Worsened	None	None
	Same as before	4	26.7

Graph 6: Patients' Qualitative Assessment of Improvement



Graph 7: Caregivers' Qualitative Assessment of Improvement



5 out of the 15 patient had motor deficits preoperatively. Three of them (60.0%) improved following surgery (one dramatically) while 2 (40.0%) were unchanged.

Table 8: Improvement in Motor Power

Motor Power	**Frequency (N=5)**	**Percentage**
Improved	3	60.0
Same as before	2	40.0
Worsened	None	None

Sub Analysis

As part of sub analysis Kruskal Wallis analysis and the Mann Whitney test were applied as appropriate to assess whether the other variables recorded – GCS at admission, interval between first admission and cranioplasty and the location of the craniectomy defect had any influence on the outcome. The results are documented in tables 9 – 12. The GCS at

admission affected only a few of the variables significantly (caregivers' KBCI, especially between the mild and moderate injuries). The interval between the first admission and cranioplasty and the location of the craniectomy deficit did not have a significant effect on the outcome.

Table 9: Kruskal Wallis analysis of Original Admission GCS

Scale	GCS Category	Median	IQ	X2	P-Value
MPAI-4	Mild	2.50	1.00-4.00	.24	.89
	Moderate	1.00	.00-9.00		
	Severe	3.50	3.00-4.00		
ACE-R	Mild	96.00	91.00-98.00	3.36	.19
	Moderate	92.50	85.00-94.00		
	Severe	89.00	87.00-91.00		
KBCI-Patient	Mild	85.00	76.00-113.00	1.28	.53
	Moderate	94.00	87.75-112.50		
	Severe	115.00	100.00-130.00		
KBCI-Relative	Mild	76.00	76.00-77.00	6.45	*.04
	Moderate	96.00	82.00-149.25		
	Severe	100.50	85.00-116.00		
MET	Mild	6.00	4.00-6.00	2.13	1.45
	Moderate	7.50	5.00-17.00		
	Severe				

Table 10: Mann-Whitney test of Admission GCS and KBCI Relatives Total Score

GCS Category	Median	U-Value	P-Value
Mild Vs. Moderate	76.00 (N=3)	**.00**	*.01
	96.00 (N=8)		
Mild Vs. Severe	76.00 (N=3)	**.00**	.08
	100.50 (N=2)		
Moderate Vs. Severe	96.00 (N=3)	**8.0**	1.00
	100.50 (N=2)		

Table 11: Kruskal Wallis analysis of Interval between Decompression and Cranioplasty

Scale	Duration Category(months)	Median	IQ	X2	P-Value
MPAI-4	7-12	1.00	01.00-04.00	.91	.63
	13-18	3.00	00.00-04.00		
	19-24	9.00	00.00-11.00		
ACE-R	7-12	94.50	91.00-96.50	5.52	.06
	13-18	91.00	86.50-94.00		
	19-24	85.50	80.50-92.75		
KBCI-Patients	7-12	90.50	82.75-104.50	3.45	.18
	13-18	92.50	82.00-122.50		
	19-24	115.00	105.00-144.00		
KBCI-Relatives	7-12	78.50	76.00-95.25	5.59	.06
	13-18	86.50	80.50-109.00		
	19-24	163.00	101.00-175.00		
MET	7-12	6.00	04.00-10.25	1.85	.40
	13-18	12.00	07.00-17.00		
	19-24	6.00	06.00-06.00		

Table 12: Mann-Whitney test of Interval and KBCI Relatives Apathy

Group	Duration Category	Median	U-Value	P-Value
I	**7-12months VS. 13-18 months**	8.0 (N=5) 10.00 (N=3)	10.00	.66
II	**7-12 months Vs. 19-24 months**	8.00 (N=5) 22.00 (N=3)	.00	*.02
III	**13-18 months Vs. 19-24 months**	10.00 (N=3) 22.00 (N=3)	1.00	.07

Table 13: Kruskal Wallis analysis of Location of Defect and Outcome

Scale	Duration Category	Median	IQ	X2	P-Value
MPAI-4	Bifrontal	4.00	1.75-9.25	1.95	.38
	Right	2.00	.25-7.50		
	Left	1.00	.00-4.00		
ACE-R	Bifrontal	91.00	84.25-94.00	.16	.92
	Right	91.50	85.25-96.50		
	Left	94.00	88.50-94.00		
KBCI-Patient	Bifrontal	105.00	89.75-128.50	1.87	.39
	Right	105.00	80.50-137.00		
	Left	89.00	82.00-98.25		
KBCI-Relative	Bifrontal	85.50	77.00-154.00	.05	.98
	Right	101.00	76.50-139.50		
	Left	86.50	80.50-103.00		
MET	Bifrontal	8.00	6.00-17.00	2.40	.30
	Right	6.00	4.00-6.00		
	Left	7.00	4.00-17.00		

DISCUSSION

Introduction

This study was designed to objectively assess the effect of cranioplasty on cognition, behaviour, executive and neurological functions in patients who initially underwent decompressive craniectomy after TBI. The hypothesis was that there would be a significant improvement following the closure of the defect in the skull. The change in function in these domains and the influence of other factors recorded are discussed below.

The effect of cranioplasty in improving cognition

The improvement in cognition after cranioplasty was assessed using ACE-R which gives better and rapid assessment of cognition when compared to other neuropsychological tests such as the MMSE. Our results showed a statistically significant improvement in total score, though significant improvement could not be demonstrated in any of the subscales (attention and orientation, memory, fluency, language, visuospatial abilities). A detailed review of literature shows there is very limited information available on the effect of cranioplasty on cognitive outcome. A study done by Anger et al showed significant improvement in major cognitive functions after cranioplasty assessed by Cognistat neuropsychological battery and EXIT interview. Another study by Grantham and Landis stated that almost every partially aphasic patient showed improvement in fluency after cranioplasty and one patient who was able to use only 10 words before cranioplasty became able to use 190 words within a week (50).

For this study one of the exclusion criteria was inability to administer the ACE-R. The ability to cooperate for this test in itself implies a fairly good level of cognition, and it is possible that by excluding patients with poorer levels of function we have eliminated those who might have shown dramatic improvement. This decision was deliberate, as assessment scales such as the Disability Rating Scale and Rancho Los Amigos score are comparatively crude measures and are used more for categorizing patients rather than serial assessment of neurological functions. This might be a reason for no statistical improvement in the subscales.

Cranioplasty and behavioral disturbances

Behavioral changes before and after cranioplasty was assessed using the behavioral change index (KBCI), which is completed by both the patient and caregiver. This tool has eight subcales of behavior: inattention, impulsivity, apathy, unawareness of problems, communication, executive, behavioral, and emotional problems. The caregiver participation is useful in cases where the patient was unaware of or denied problems.

The result of patients' KBCI reveals improvement in apathy, somatic problems and emotional problems, and no changes in the other subscales or total scores. However the patients' caregivers showed that they perceived an improvement in overall behaviour as well as in communication and somatic problem subscales

The existing evidence on effect of cranioplasty in changing behavior reveals conflicting results. Primrose reviewed 42 cases, 19 of whom were cured of their complaints, eight improved, five were unchanged, and two made worse. Shuttleworth reported seven cases, four of whom were relieved of their complaints and two improved, while one was unchanged (13). There are several studies showing improvement in headache after cranioplasty (13,14,16,27,37).

On the other hand, Termier followed 63 cases after cranioplasty and found that only a few psychotic patients had improved, though there was improvement in other aspects of the trephine syndromes (13). Similarly, Lockhart et al stated that precranioplasty headaches, visual disturbances, difficulty in speech, convulsions, weakness of extremities and mental impairment were not changed by the repair of the cranial defect. (39)

Cranioplasty and executive function

Improvement in basic cognition should have positive effect on executive functions, but while there is literature showing enhanced basic cognitive functions after cranioplasty there is no study demonstrating improvement in executive functions. In this study the change in executive function after cranioplasty has been determined using the MET, which assesses executive functions in real life situations. The total score of MET as well as the rule breaks subscale showed that there was a significant improvement in executive function after cranioplasty. Therefore cranioplasty has a positive effect not only on basic cognitive functions but on executive functions as well. This improvement is also reflected in the significant improvement noted in MPAI4 domains of ability, adjustment and participation index, which are a direct result of improved executive functions.

Cranioplasty and functional outcome

The MPAI-4 is a four part assessment measure designed to evaluate a range of physical, cognitive, emotional, behavioral and social problems that patients confront during recovery from injury. The MPAI-4 provides measures of ability, adjustment and participation skill of patients.

The results of our study shows there is a significant improvement in these functional outcome measures (ability, adjustment and participation) after cranioplasty. There is improvement, though not achieving statistical significance, in mobility, communication, self care and fund of information. Similarly adjustment also shows improvement in components of emotion, headache, fatigue, dizziness, vision and audition, and participation (the third component) showed improvement in social, vocational and familial dimensions of the index.

Existing literature has shown improvement in speech, headache, apathy, fatigability and anger similar to our study (13, 14, 21, 50). However, Lockhart et al stated that pre cranioplasty headaches, visual disturbances, difficulty in speech, convulsions, weakness of extremities and mental impairment were not changed by the repair of the cranial defect (39).

Cranioplasty and motor function

In our study five patients had motor weakness before cranioplasty. Among the five patients 3 patients (60%) showed improvement in motor power and 2 patients (40%) remained unchanged after cranioplasty. One of the patients showed dramatic improvement, improving his hand function from unusable to fully functional. Similar results have been reported by Chang et al., with improvement in motor deficit in 3 out of 4 patients (34). There are several other studies which also report improvement in motor deficits after cranioplasty (14, 20, 21, 37,50). However Lockhart et al showed no change in motor function after cranioplasty (39).

Improvement after cranioplasty and severity of original injury

To examine the effect of initial impact on the outcome after cranioplasty, patients were divided into three groups according the GCS score at the time of brain injury. The only positive finding in this analysis was that the KBCI caregiver's score showed significant improvement in behavior among the mild head injury patients as compared to moderate head injured patients. Hence, it can be concluded that the initial impact of trauma at the time head injury did not have effect on cognitive, executive, or functional outcome after cranioplasty.

Interval between injury and cranioplasty

The influence of the timing of cranioplasty after the decompression is unknown. We divided patients into three groups according the time duration between the decompressive surgery and cranioplasty, and analysed outcomes in these groups. The only significant influence of the interval was on the caregivers' perception of behavior, while all other tests showed no difference. Hence, we can conclude that once a patient has become neurologically stable the timing of cranioplasty will not have significant effect on cognition, functional and executive outcome.

Cranioplasty and location of defect

The location of the decompression had no influence on the degree of improvement. This is probably because each patient in this study acts as his own control, and the deficit improvement is from their own baseline.

Subjective assessment of improvement

Patients and caregivers were asked to fill out a qualitative assessment scale to assess their impression of change after surgery. Out of 15 patients, 13 (86.7%) reported

improvement, 1 patient (6.7%) reported worsening after surgery and 1 patient (6.7%) reported no change. On the same scale 11 (73.3%) caregivers reported improvement and 4 (26.7%) no change. None of the caregivers found any worsening. Thus the majority of patients and caregivers felt there was improvement after surgery.

CONCLUSIONS

1. Cranioplasty results in statistically significant improvement in components of motor, cognitive, behavioural and executive functions, with a corresponding improvement in the functional outcome of the patient.
2. Location of defect, interval between surgery and cranioplasty and initial severity of injury did not have any impact on the outcome after cranioplasty.

Strength of the study

The present study holds many strong points which makes the study more relevant and reliable. The current study is a pioneer study in India having a comprehensive approach in terms of outcome measure, which covers most of domains, physical, mental, social, and environmental, mentioning in international classification of functioning. Secondly, it can be considered as a pilot study for a further detailed study of improvement in cognition, behavior, executive function, motor function and functional outcome after cranioplasty with appropriate psychometric tests in a systemic manner. Apart from that, the study design makes the study more reliable by selecting the patients for cranioplasty after a stable ACE-R score. The tools used for assessing cognition and functional outcome variables are universally standardized and have sensitivity and specificity. The MET, test used in the study, taping the executive functioning by asking the patient to do certain real life situation rather than laboratory test, which makes known changes in real life. Similarly, the other tests ACE-R and MPAI-4, are free of inter rater bias since pre and post assessment had done by different well

trained staffs. As part of managing bias, the cognitive assessment was done independently from the team that carried out the surgical procedure. Besides, patients and relatives were not informed about the possible improvement which prevented the occurrence of placebo effect.

Limitations and suggestions for future study

Although the study has been conducted keeping in mind all the procedures and pitfalls of research, certain limitation has crept into it. First, the size of the sample is small. Hence, caution is warranted while interpreting the results. Selection of large sample size, in future studies, is required to rectify the problem. Also, future studies would benefit from different control group. Second, duration of follow up, i.e., three months, can be inadequate post assessment period. In further studies, increasing the post assessment period will give more reliable result. Third, the sampling technique employed for the study is purposive sampling which is uncertain in normal distribution. It can be rectified by using non-purposive sampling technique or conducting a randomized controlled trial for further studies.

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Appendix 1: PREOPERATIVE PROFORMA

CHANGES IN COGNITIVE AND NEUROLOGICAL FUNCTIONS IN PATIENTS UNDERGOING CRANIOPLASTY FOR LARGE CRANIOTOMY DEFECTS

Name: **Hospital Number:** **Unit:**

Age: **Sex:**

Address:

Date of Trauma:

GCS before surgery: **GCS at discharge:**

Date of decompressive craniectomy: **Date of cranioplasty:**

Time interval between decompressive craniectomy & cranioplasty:

1. Mayo-Portland Adaptability Inventory-4

	Ability	**Adjustment**	**Participation**	**Pre existing and associated condition**
Preop score				
Postop score				

2. ACE – R (Pre operative)

	1	2	3	4	5
Date					
Score					

3. ACE – R (Post operative)

Date	
Score	

4. MOTOR POWER-(Pre operative)

	R UL	L UL		R LL	L LL
Shoulder-Flexion			Hip -Flexion		
-Extension			Extension		
Elbow -Flexion			Knee -Flexion		
-Extension			Extension		
Wrist -Flexion			Ankle D.Flexion		
-Extension			P.Flexion		
Hand grip					

5. MOTOR POWER-(Postoperative);

	R UL	L UL		R LL	L LL
Shoulder-Flexion			Hip -Flexion		
-Extension			Extension		
Elbow -Flexion			Knee -Flexion		
-Extension			Extension		
Wrist -Flexion			Ankle D.Flexion		
-Extension			P.Flexion		
Hand grip					

6. KBCI

	Preop	Postop
Inattention		
Impulsivity		
Unawareness of problems		
Apathy		
Interpersonal difficulties		
Communication problems		
Somatic difficulties		

Note:

7. MET:

	Preop	Postop
Inefficiencies		
Rule breaks		
Task failures		
Interpretation failures		
Total Numbers of errors		

SUBJECTIVE ASSESSMENT:

Patient's subjective assessment post cranioplasty: Improvement/No improvement

Caregiver's subjective assessment post cranioplasty: Improvement/No improvement

Appendix 2 : INFORMED CONSENT

Patient information.

Cranioplasty is a surgical procedure performed on patients where a portion of the skull removed during the first surgery is replaced by artificial bone. Other than cosmetic and protective function some studies suggest that this surgical procedure of replacing the skull bone has added benefits related to improvements in neurological function, particularly in the ability of a patient to understand, plan and execute specified acts. In order to study the effect of this procedure the patient will be evaluated via a physical exam and a written cognitive test before and three months after surgery. The surgical procedure involved in this study is not different and is routinely practiced. The assessment will be performed prior to the operation and for one month afterwards serially for three months.

The data thus collected will be used for the benefit of future patients. The data thus obtained will be accessed by the investigators of the study, ethics committee and the publishers (in case the study is published later). However, the patient's identity will not be revealed in any information released to third parties or published. If you are willing to participate in this study, you would have to be willing to agree to a physical examination and a cognitive assessment before and 3 months after surgery.

However, this participation is entirely voluntary and your care in this hospital will not be affected by your decision. If you are willing you are required to give your consent by signing the following form. You have the right to withdraw from the study at any time.

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am

free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature of the Witness: _____

Date:_____/_____/_____

Name of the Witness: _____

Appendix 3: QUALITATIVE DATA SHEET

Name of Patient: Date:

For Patient

Do you feel any significant change after cranioplasty?

Improved / Same / Worse

If so please explain:

For Relative

Do you find any significant change in the patient after cranioplasty?

Improved / Same / Worse

If so please explain:

Appendix-4: MAYO PORTLAND ADAPTIBILITY INVENTORY-4 (MPI-4)

Mayo-Portland Adaptability Inventory-4

Muriel D. Lezak, PhD, ABPP & James F. Malec, PhD, ABPP

Name: _____ Clinic # _____ Date _____

Person reporting (circle one): Single Professional Professional Consensus Person with brain injury Significant other: _____

Below each item, circle the number that best describes the level at which the person being evaluated experiences problems. Mark the greatest level of problem that is appropriate. Problems that interfere rarely with daily or valued activities, that is, less than 5% of the time, should be considered not to interfere. Write comments about specific items at the end of the rating scale.

For Items 1-20, please use the rating scale below.

0 None	1 Mild problem but does not interfere with activities; may use assistive device or medication	2 Mild problem; interferes with activities 5-24% of the time	3 Moderate problem; interferes with activities 25-75% of the time	4 Severe problem; interferes with activities more than 75% of the time

Part A. Abilities

1. **Mobility**: Problems walking or moving; balance problems that interfere with moving about
   0 1 2 3 4
2. **Use of hands**: Impaired strength or coordination in one or both hands
   0 1 2 3 4
3. **Vision**: Problems seeing; double vision; eye, brain, or nerve injuries that interfere with seeing
   0 1 2 3 4
4. ***Audition**: Problems hearing; ringing in the ears
   0 1 2 3 4
5. **Dizziness**: Feeling unsteady, dizzy, light-headed
   0 1 2 3 4
6. **Motor speech**: Abnormal clearness or rate of speech; stuttering
   0 1 2 3 4

7A. **Verbal communication**: Problems expressing or understanding language
   0 1 2 3 4

7B. **Nonverbal communication**: Restricted or unusual gestures or facial expressions; talking too much or not enough; missing nonverbal cues from others
   0 1 2 3 4

8. **Attention/Concentration**: Problems ignoring distractions, shifting attention, keeping more than one thing in mind at a time
   0 1 2 3 4
9. **Memory**: Problems learning and recalling new information
   0 1 2 3 4
10. **Fund of Information**: Problems remembering information learned in school or on the job; difficulty remembering information about self and family from years ago
    0 1 2 3 4
11. **Novel problem-solving**: Problems thinking up solutions or picking the best solution to new problems
    0 1 2 3 4
12. **Visuospatial abilities**: Problems drawing, assembling things, route-finding, being visually aware on both the left and right sides
    0 1 2 3 4

Part B. Adjustment

13. **Anxiety**: Tense, nervous, fearful, phobias, nightmares, flashbacks of stressful events
    0 1 2 3 4
14. **Depression**: Sad, blue, hopeless, poor appetite, poor sleep, worry, self-criticism
    0 1 2 3 4
15. **Irritability, anger, aggression**: Verbal or physical expressions of anger
    0 1 2 3 4
16. ***Pain and headache**: Verbal and nonverbal expressions of pain; activities limited by pain
    0 1 2 3 4
17. **Fatigue**: Feeling tired; lack of energy; tiring easily
    0 1 2 3 4
18. **Sensitivity to mild symptoms**: Focusing on thinking, physical or emotional problems attributed to brain injury; rate only how concern or worry about these symptoms affects current functioning over and above the effects of the symptoms themselves
    0 1 2 3 4
19. **Inappropriate social interaction**: Acting childish, silly, rude, behavior not fitting for time and place
    0 1 2 3 4
20. **Impaired self-awareness**: Lack of recognition of personal limitations and disabilities and how they interfere with everyday activities and work or school
    0 1 2 3 4

Use scale at the bottom of the page to rate item #21

21. **Family/significant relationships**: Interactions with close others; describe stress within the family or those closest to the person with brain injury; "family functioning" means cooperating to accomplish those tasks that need to be done to keep the household running

0 Normal stress within family or other close network of relationships	1 Mild stress that does not interfere with family functioning	2 Mild stress that interferes with family functioning 5-24% of the time	3 Moderate stress that interferes with family functioning 25-75% of the time	4 Severe stress that interferes with family functioning more than 75% of the time

MPAI-4 3/31/03

Part C. Participation

22. Initiation: Problems getting started on activities without prompting

0 None	1 Mild problem but does <u>not</u> interfere with activities; may use assistive device or medication	2 Mild problem; interferes with activities 5-24% of the time	3 Moderate problem; interferes with activities 25-75% of the time	4 Severe problem; interferes with activities more than 75% of the time

23. Social contact with friends, work associates, and other people who are not family, significant others, or professionals

0 Normal involvement with others	1 Mild difficulty in social situations but maintains normal involvement with others	2 Mildly limited involvement with others (75-95% of normal interaction for age)	3 Moderately limited involvement with others (25-74% of normal interaction for age)	4 No or rare involvement with others (less than 25% of normal interaction for age)

24. Leisure and recreational activities

0 Normal participation in leisure activities for age	1 Mild difficulty in these activities but maintains normal participation	2 Mildly limited participation (75-95% of normal participation for age)	3 Moderately limited participation (25-74% of normal participation for age)	4 No or rare participation (less than 25% of normal participation for age)

25. Self-care: Eating, dressing, bathing, hygiene

0 Independent completion of self-care activities	1 Mild difficulty, occasional omissions or mildly slowed completion of self-care; may use assistive device or require occasional prompting	2 Requires a little assistance or supervision from others (5-24% of the time) including frequent prompting	3 Requires moderate assistance or supervision from others (25-75% of the time)	4 Requires extensive assistance or supervision from others (more than 75% of the time)

26. Residence: Responsibilities of independent living and homemaking (such as, meal preparation, home repairs and maintenance, personal health maintenance beyond basic hygiene including medication management) but <u>not</u> including managing money (see #29)

0 Independent; living without supervision or concern from others	1 Living without supervision but others have concerns about safety or managing responsibilities	2 Requires a little assistance or supervision from others (5-24% of the time)	3 Requires moderate assistance or supervision from others (25-75% of the time)	4 Requires extensive assistance or supervision from others (more than 75% of the time)

27. *Transportation

0 Independent in all modes of transportation including independent ability to operate a personal motor vehicle	1 Independent in all modes of transportation, but others have concerns about safety	2 Requires a little assistance or supervision from others (5-24% of the time); cannot drive	3 Requires moderate assistance or supervision from others (25-75% of the time); cannot drive	4 Requires extensive assistance or supervision from others (more than 75% of the time); cannot drive

28A. *Paid Employment: Rate either item 28A or 28B to reflect the primary desired social role. Do not rate both. Rate 28A if the primary social role is paid employment. If another social role is primary, rate only 28B. For both 28A and 28B, "support" means special help from another person with responsibilities (such as, a job coach or shadow, tutor, helper) or reduced responsibilities. Modifications to the physical environment that facilitate employment are not considered as support.

0 Full-time (more than 30 hrs/wk) without support	1 Part-time (3 to 30 hrs/ wk) without support	2 Full-time or part-time with support	3 Sheltered work	4 Unemployed; employed less than 3 hours per week

28B. *Other employment: Involved in constructive, role-appropriate activity other than paid employment.
Check only one to indicate <u>primary</u> desired social role: Childrearing/care-giving Homemaker, no childrearing or care-giving Student Volunteer Retired (Check retired only if over age 60; if unemployed, retired as disabled and under age 60, indicate "Unemployed" for item 28A.

0 Full-time (more than 30 hrs/wk) without support; full-time course load for students	1 Part-time (3 to 30 hrs/ wk) without support	2 Full-time or part-time with support	3 Activities in a supervised environment other than a sheltered workshop	4 Inactive; involved in role-appropriate activities less than 3 hours per week

29. Managing money and finances: Shopping, keeping a check book or other bank account, managing personal income and investments; if independent with small purchases but not able to manage larger personal finances or investments, rate 3 or 4.

0 Independent, manages small purchases and personal finances without supervision or concern from others	1 Manages money independently but others have concerns about larger financial decisions	2 Requires a little help or supervision (5-24% of the time) with large finances; independent with small purchases	3 Requires moderate help or supervision (25-75% of the time) with large finances; some help with small purchases	4 Requires extensive help or supervision (more than 75% of the time) with large finances; frequent help with small purchases

MPAI-4 3/31/03

Part D: Pre-existing and associated conditions. The items below do not contribute to the total score but are used to identify special needs and circumstances. For each rate, pre-injury and post-injury status.

30. Alcohol use: Use of alcoholic beverages.

Pre-injury _____ Post-injury _____

0	No or socially acceptable use	1	Occasionally exceeds socially acceptable use but does not interfere with everyday functioning; current problem under treatment or in remission	2	Frequent excessive use that occasionally interferes with everyday functioning; possible dependence	3	Use or dependence interferes with everyday functioning; additional treatment recommended	4	Inpatient or residential treatment required

31. Drug use: Use of illegal drugs or abuse of prescription drugs.

Pre-injury _____ Post-injury _____

0	No or occasional use	1	Occasional use does not interfere with everyday functioning; current problem under treatment or in remission	2	Frequent use that occasionally interferes with everyday functioning; possible dependence	3	Use or dependence interferes with everyday functioning; additional treatment recommended	4	Inpatient or residential treatment required

32. Psychotic Symptoms: Hallucinations, delusions, other persistent severely distorted perceptions of reality.

Pre-injury _____ Post-injury _____

0	None	1	Current problem under treatment or in remission; symptoms do not interfere with everyday functioning	2	Symptoms occasionally interfere with everyday functioning but no additional evaluation or treatment recommended	3	Symptoms interfere with everyday functioning; additional treatment recommended	4	Inpatient or residential treatment required

33. Law violations: History before and after injury.

Pre-injury _____ Post-injury _____

0	None or minor traffic violations only	1	Conviction on one or two misdemeanors other than minor traffic violations	2	History of more than two misdeameanors other than minor traffic violations	3	Single felony conviction	4	Repeat felony convictions

34. Other condition causing physical impairment: Physical disability due to medical conditions other than brain injury, such as, spinal cord injury, amputation. Use scale below #35.

Pre-injury _____ Post-injury _____

35. Other condition causing cognitive impairment: Cognitive disability due to nonpsychiatric medical conditions other than brain injury, such as, dementia, stroke, developmental disability.

Pre-injury _____ Post-injury _____

0	None	1	Mild problem but does not interfere with activities; may use assistive device or medication	2	Mild problem; interferes with activities 5-24% of the time	3	Moderate problem; interferes with activities 25-75% of the time	4	Severe problem; interferes with activities more than 75% of the time

Comments:

Item #

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

MPAI-4 3/31/03

Appedix-5: ADDENBROOKE'S COGNITIVE EXAMINATION-R (ACE-R)

ADDENBROOKE'S COGNITIVE EXAMINATION - ACE-R

Tamil Version

Name / Age /Sex/ Hospital No:

Dates of testing: ____/____/____/____

Handedness:

Tester's names: ____

Education: ____

Occupation: ____

ORIENTATION

Ask: What is the	DAY NAAL நாள்	DATE(+/-2) THEDHI தேதி	MONTH MASAM மாதம்	YEAR VARUSHAM வருடம்	SEASON PARUVAM பருவம்	[Score 0-5]
Ask: Which	BUILDING KATTIDAM கட்டிடம்	FLOOR MAADI தளம் /மாடி	TOWN OOR ஊர்	STATE MAANILAM மாநிலம்	COUNTRY DHESAM தேசம்	[Score 0-5]

REGISTRATION

[Score 0-3]

Tell: 'I'm going to give you three words and I'd like you to repeat after me: lemon, key and ball'. After subject repeats, say 'Try to remember them because i'm going to ask you later'. Score only the first trial (repeat 3 times if necessary). **எலுமிச்சை, சாவி, பந்து** (Elumichai, Saavi, Pandhu)

Register number of trials .....

ATTENTION& C ONCENTRATION

[Score 0-5]

Ask the subject: ' could you take 7 away from a 100? After the subject responds, ask him or her to take away another 7 to a total of 5 subtractions. If subject make a mistake, carry on and check the subsequent answer (i.e. 93, 84, 77, 70, 63 -score 4) Stop after five subtractions (93, 86, 79, 72, 65). (Score for the best performed task).....

Ask: 'Could you please spell **WORLD (மத்தளம்)** Mathalam. Then ask him/her to spell it backwards:

ATTENTION&ORIENTATION

MEMORY - Recall

[Score 0-3]

Ask: 'Which 3 words did I ask you to repeat and remember?'.....

MEMORY - Anterograde Memory

[Score 0-7]

- Tell: ' I'm going to give you a name and address and I'd like you to repeat after me. We'll be doing that 3 times, so you have a chance to learn it. I'll be asking you later'
  Score only the third trial

	1st Trial	2nd Trial	3rd Trial
Selva Kumar 42, Nehru Street Gandhinagar Vellore			

MEMORY - Retrograde Memory

[Score 0 -4]

- Name of current Prime Minister .....
- Name of the woman who was Prime Minister/capital of India .....
- Name of the Indian president/CM of your state/Local municipal officer/VAO .....
- Name of the Indian Prime minister who was killed in bomb blast in 1991 .....

MEMORY

VERBAL FLUENCY - Letter 'P' and animals

➢ **Letters**

Say: 'I'm going to give you a letter of the alphabet and I'd like you to generate as many words As you can beginning with that letter, but not names of people or places. Are you ready? You've got a minute and the letter is 'ப(Pa)' , 'P'

[Score 0 - 7]

				>17	7
				14-17	6
				11-13	5
				8-10	4
				6-7	3
				4-5	2
				2-3	1
				<2	0
				total	correct

➢ **Animals**

Say: 'Now can you name as many animals as possible, beginning with any letter? You've got a minute

[Score 0 - 7]

				>21	7
				17-21	6
				14-16	5
				11-13	4
				9-10	3
				7-8	2
				5-6	1
				<5	0
				total	correct

LANGUAGE - Comprehension

➢ Show written instruction: (Kanngalai Moodavaum)

[Score 0-1]

Close your eyes

கண்களை மூடவும்

➢ 3 stage command: (Score 1 for each command)

'Take the paper in your right hand. Fold the paper in half. Put the paper on the floor'

Score 0-3]

LANGUAGE - Writing

➢ Ask the subject to make up a sentence and write it in the space below: Score 1 if sentence contains a subject and a verb and meaning. (Give a pen with closed cap)

[Score 0-1]

LANGUAGE - Repetition

[Score 0-2]

➢ Ask the subject to repeat:' **Hippopotamus'; 'Eccentricity; 'Unintelligible'; 'Statistician'**
Score 2 if all correct; 1 if 3 correct; 0 if 2 or less. **(வண்டு கரங்கள் குரல்வளை வளையல்)**
(Vandu, Karangal, Kuralvalai, Valayal)

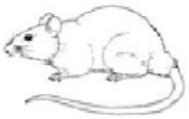
➢ Ask the subject to repeat: **'Above, beyond and below'** [Score 0-1]
'கற்க கசடற கற்பவை'(Karaka, Kasadara, Karpavai)

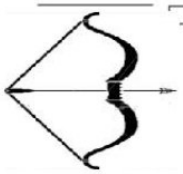
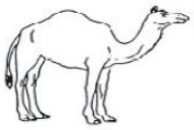
➢ Ask the subject to repeat: **'No ifs, ands or buts'** [Score 0-1]
'வானில் வானவில் தெரியும்' (Vaanil Vaanavil Theriyum)

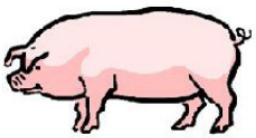
LANGUAGE - Naming

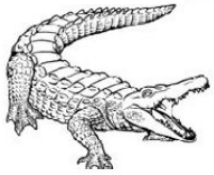
➢ Ask the subject to name the following pictures: [Score 0-2]
Pencil
+Watch







[Score 0-10]




LANGUAGE

LANGUAGE - Comprehension

➢ Using the pictures above, ask the subject to: [Score 0-4]

- Point to the one which is found in desert (paalaivanam) .....
- Point to the one which can fly .....
- Point to the one which is used by warriors .....
- Point to the one which is worn by king/Queen .....

LANGUAGE - Reading

LANGUAGE

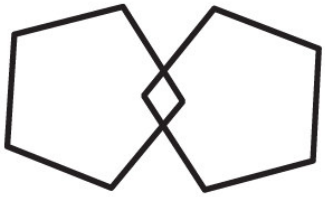
- **Ask the subject to read the following words: [Score 1 only if all correct]** [Score 0-1]

sew	மரம் (Maram)
pint	ஆறு (Aaru)
soot	வேஷம் (Vesham)
dough	சாஸ்திரம் (Sasthram)
height	நிறம் (Niram)

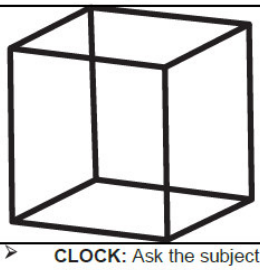
VISUOSPATIAL ABILITIES

VISUOSPATIAL

- **Overlapping pentagons:** Ask the subject to copy this diagram: (Pentagon should show 5 corners) [Score 0-1]



- **Wire cube:** Ask the subject to copy this drawing (if cube has 12 lines =2, less than 12 lines =1) [Score 0-2]



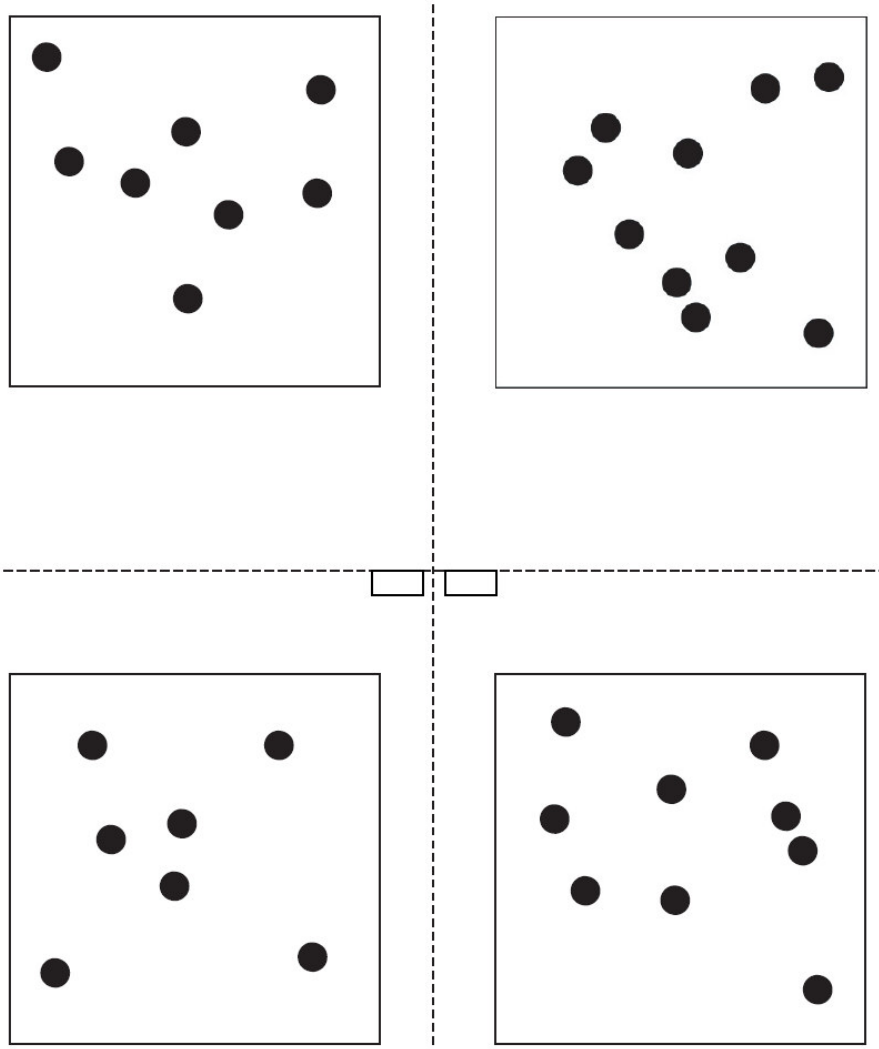
- **CLOCK:** Ask the subject to draw a clock face with numbers and the hands at ten past five. (For scoring circle = 1, numbers = 2, hands = 2 if all correct) [Score 0-5]

PERCEPTUAL ABILITIES

VISUOSPATIAL

- Ask the subject to count the dots without pointing them (Mask the other pictures)

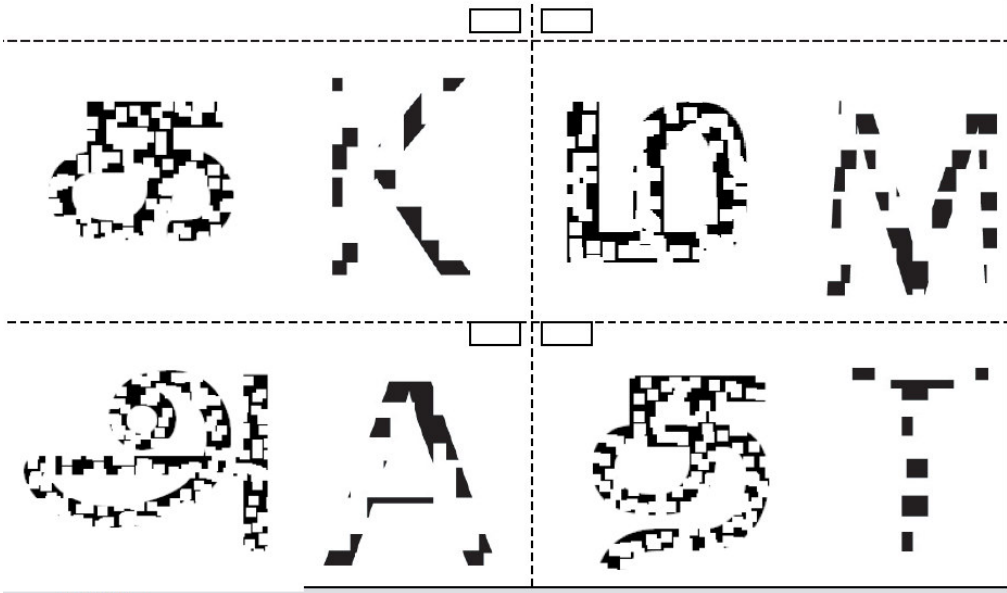
[Score 0-4]



ADDENBROOKE'S COGNITIVE EXAMINATION - ACE-R

PERCEPTUAL ABILITIES

➢ Ask the subject to identify the letters (Mask the other pictures) [Score 0-4]



VISUOSPATIAL

RECALL

➢ Ask "now tell me what you remember of that name and address we were repeating at the beginning"

Selva **Kumar** ------
42 **Nehru Street** -------
Gandhinagar ------
Vellore ------

[Score 0-7]

MEMORY

RECOGNITION

➢ **This test should be done if subject failed to recall one or more items. If all items were recalled, skip the test and score 5. If only part is recalled start by ticking items recalled in the shadowed column on the right hand side. Then test not recalled items by telling "ok, I'll give you some hints: was the name X, Y or Z?" and so on. Each recognised item scores one point which is added to the point gained by recalling.**

[Score 0-5]

Nalla Kumar		**Selva Kumar**		Selva Krishna		recalled	
43		**42**		49		recalled	
Nehru Road		Patel road		**Nehru Street**		recalled	
Virudhunagar		**Gandhinagar**		Chrompet		recalled	
Nellore		Nagpur		**Vellore**		recalled	

General Scores

MMSE ~~/30~~
ACE-R /100

SCORE

Subscores		Date	Date	Date	Date
Attention and Orientation	/18				
Memory	/26				
Fluency	/14				
Language	/26				
Visuospatial	/16				
	Total				

Appendix-6: KEY BEHAVIOR CHANGE INVENTORY (KBCI)

Key Behavior Change Inventory (KBCI)

This version is to be completed by the PATIENT or individual who sustained some type of injury to describe the CURRENT LEVEL OF FUNCTIONING.

Name: _____ Today's Date: _____

Birthdate: _____

Age: _____

Gender: Male Female

Type of Injury:
_____

_____
___

Date of Injury: _____

Please read the following items and answer them

as to how they apply to you at this time.

KBCI: Self-Rating Version: Current Functioning

Patient's Name: _____

The following is a series of statements that can apply to people. We would like to know how well each of these statements describes you. Read each statement carefully and decide how well that statement fits you. Mark your answers by circling a response according to the following key:

F = False, not at all
ST = Slightly True
MT = Mostly True
VT = Very True

	I:				
1.	usually remember appointments, chores, and things I need to do	F	ST	MT	VT
2.	plan things out ahead of time	F	ST	MT	VT
3.	care about other people	F	ST	MT	VT
4.	have very little interest in things	F	ST	MT	VT
5.	frequently feel tired	F	ST	MT	VT
6.	know my limitations	F	ST	MT	VT
7.	often don't get the humor in jokes	F	ST	MT	VT
8.	seem happy most of the time	F	ST	MT	VT
9.	have trouble following directions	F	ST	MT	VT
10.	say or do the first thing that comes to mind	F	ST	MT	VT
11.	get into arguments easily	F	ST	MT	VT
12.	frequently sit for long periods of time and do nothing	F	ST	MT	VT
13.	feel dizzy	F	ST	MT	VT
14.	get into trouble and don't understand why	F	ST	MT	VT
15.	say things that don't make much sense	F	ST	MT	VT
16.	have an even temper	F	ST	MT	VT
17.	misplace and lose things	F	ST	MT	VT
18.	am deliberate and careful	F	ST	MT	VT
19.	do things without thinking about other people's feelings	F	ST	MT	VT
20.	need encouragement to do things	F	ST	MT	VT

F = False, not at all
ST = Slightly True
MT = Mostly True
VT = Very True

	I:				
21.	am not overly concerned about my health	F	ST	MT	VT
22.	have poor insight into my problems	F	ST	MT	VT
23.	talk too much	F	ST	MT	VT
24.	am positive about the future	F	ST	MT	VT
25.	get confused easily	F	ST	MT	VT
26.	act unpredictably	F	ST	MT	VT
27.	am polite in social situations	F	ST	MT	VT
28.	am creative	F	ST	MT	VT
29.	frequently have headaches	F	ST	MT	VT
30.	can recognize when I am beginning to get upset	F	ST	MT	VT
31.	talk too loudly or softly	F	ST	MT	VT
32.	am easily hurt by criticism	F	ST	MT	VT
33.	have trouble with details	F	ST	MT	VT
34.	am too hasty in my actions	F	ST	MT	VT
35.	am sensitive to other people's feelings and needs	F	ST	MT	VT
36.	get little pleasure out of life	F	ST	MT	VT
37.	don't let normal aches and pains bother me	F	ST	MT	VT
38.	think I can do things I really can't	F	ST	MT	VT
39.	listen carefully and respond normally when talking with others	F	ST	MT	VT
40.	feel worthless	F	ST	MT	VT
41.	concentrate easily on what I am doing	F	ST	MT	VT
42.	often act without thinking	F	ST	MT	VT
43.	am self-centered	F	ST	MT	VT
44.	am enterprising and energetic	F	ST	MT	VT
45.	often do not feel well	F	ST	MT	VT

F = False, not at all
ST = Slightly True
MT = Mostly True
VT = Very True

	I:				
46.	don't realize it when my actions are not getting the job done	F	ST	MT	VT
47.	speak at an appropriate volume and speed	F	ST	MT	VT
48.	am moody and irritable	F	ST	MT	VT
49.	am attentive and sharp	F	ST	MT	VT
50.	cannot wait patiently	F	ST	MT	VT
51.	try to see how much I can get away with	F	ST	MT	VT
52.	think about the future and set goals for myself	F	ST	MT	VT
53.	usually feel dissatisfied with my medical treatment	F	ST	MT	VT
54.	recognize when others are having trouble following what I am saying	F	ST	MT	VT
55.	talk in a way that makes sense (it is easy to follow my train of thought)	F	ST	MT	VT
56.	cope poorly with stress	F	ST	MT	VT
57.	am able to focus on a chore or task until finished	F	ST	MT	VT
58.	carefully think things through	F	ST	MT	VT
59.	get along well with other people	F	ST	MT	VT
60.	have good ideas and work on them	F	ST	MT	VT
61.	use health problems as an excuse to avoid chores or duties	F	ST	MT	VT
62.	realize errors and mistakes, and try to correct them when they occur	F	ST	MT	VT
63.	stick to the topic when talking to others	F	ST	MT	VT
64.	adjust well to life's difficulties	F	ST	MT	VT

Appendix-7: MULTIPLE ERRAND'S TEST (MET)

MET

Instructions For the Participants

In this exercise you have to complete three tasks

Task I Do the following 6 things

1. Collect something for the examiner from the secretarary and do what is necessary.
2. Buy one Rs.5/- stamp from the secretarary.
3. Buy a post cover from canteen.
4. Buy a packet of mango/Apple juice.
5. Telephone at reception from inside the centre and say who you are, where you are, and what is the time. (Telephone no. 4549)
6. Post some thing for Suhany. (Post Box is inside the secretararie's cabin)

Task II Collect the following information and write down in the space below:

1. What is the closing time of pharmacy on Saturday?
2. What is the opening time of cash counter?
3. What is the price of a packet of glucose?
4. How many main entrances are there in this campus?

Task III You must meet the PMR receptionist after 30 minutes and tell the time

Tell the person observing when you have completed the exercise.

The rules you must follow:

- You must carry out all these tasks but may do so in any order.
- You should spend no more than Rs.40/-.
- You should not enter any of the hospital wards or "staff only" areas.
- No building should be entered other than to complete part of the task inside.

- Take as little time to complete this exercise without rushing excessively.
- Do not speak to the person observing you unless this is part of the exercise.

Your examiner is:

Suhany B T

Psychologist

PMR, Bagayam, CMC

Vellore, Tamil Nadu.

Space to write down answer:

You will be provided with

1. Instruction sheet
2. A pen
3. Carrier bag
4. Rs.40/-
5. Watch

How well you have done the task

1 2 3 4 5 6 7 8 9 10

Hopeless Excellent

MET SCORING SHEET

DPMR, CMC, Vellore

Quantitative Analysis	
Inefficiencies	
Rule breaks	
Task failures	
Interpretation failures	
Total number of errors	